



Participant Manual

MOH TT Certified “Same-Visit” HIV Testing Workshop

29 Nov-1 Dec 2005



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Materials Used in this Workshop

The materials used in this workshop were originally introduced at a meeting in Atlanta, Georgia on January 27-28, 2005. The meeting was entitled *“Coordinating a Systematic Roll-Out of an HIV Rapid Test Training Package: Training for Quality HIV Rapid Testing in an Era of Expanding Services”*. CAREC was represented at the meeting by Ms. Wendy Kitson-Piggott, Ms. Carol Trotman and Dr. Lynette Berkeley.

The materials introduced in Atlanta resulted from efforts coordinated among WHO, PAHO, CDC and USAID. The original materials were intended for customization to “site-specific” use. Site-specific materials must suit the training needs of national HIV rapid testing programs. In September 2004, The Ministry of Health of Trinidad and Tobago (MOH TT) requested CAREC technical assistance with introduction of “same visit” HIV testing. The customized materials in this binder are part of the CAREC response to that request.

The materials in your participant manual were customized during a series of conference calls. The goal of the customization process was to create materials optimally useful to the MOH TT “same-visit” rapid testing implementation. Those involved in the customization process are listed below. This workshop is the first use of the training package in the Caribbean Region.

The original materials included 16 Modules. This participant binder contains customized version of the Modules in their original order. Module 14 is intentionally omitted.

Customization Committee

Ms. Cameile Ali (consultant)
Dr. Lynette Berkeley (CAREC)
Ms. Rosemary Gonzales (NWRHA)
Dr. Stacy Howard (CDC)
Dr. Loris Hughes (CDC)
Ms. Peggy Mitchell (TPHL)
Dr. Cynthia Warner (CDC)
Ms. Robin Weaver (CAREC)
Dr. Katy Yao (CDC)

Status of HIV/AIDS Trinidad & Tobago

Dr Nilesch Buddha

UN Volunteer, National Surveillance Unit

Ministry of Health, Trinidad & Tobago

Challenges of tracking HIV/AIDS

- HIV diseases can be asymptomatic for years
- Many infected do not know, are not counted
- Reported data reflect testing/ care seeking behaviour & access to testing/ treatment
- Stigma, fear of loss of confidentiality and of fatal disease – create barriers
- HIV & AIDS represent same viral infection, but are reported differently – challenging to standardize reports & analysis

Challenges...(contd)

- Different sources report HIV infections, AIDS cases & deaths
- Sensitive personal data, confidential, encoding-decoding, chances of duplication
- Marginalized populations (don't want to be identified)
- Overseas/ private sector

Limitations

- HIV positive are *only* those cases which are reported/confirmed by TPHL/CAREC
- AIDS cases are
 - picked-up by NSU Surveillance Nurses from 5 public hospitals
 - classified by Medical Epidemiologist from TPHL forms
- Surveillance data do not represent HIV Incidence and Prevalence

Regional HIV and AIDS statistics and features, end of 2004

| | Adults & children living with HIV | Adults & children newly infected with HIV | Adult prevalence | Adult & child deaths due to AIDS |
|-------------------------------|--|---|-----------------------|------------------------------------|
| Sub-Saharan Africa | 25.4 million [23.4 – 28.4 million] | 3.1 million [2.7 – 3.8 million] | 7.4 [6.9 – 8.3] | 2.3 million [2.1 – 2.6 million] |
| North Africa & Middle East | 540 000 [230 000 – 1.5 million] | 92 000 [34 000 – 350 000] | 0.3 [0.1 – 0.7] | 28 000 [12 000 – 72 000] |
| South and South-East Asia | 7.1 million [4.4 – 10.6 million] | 890 000 [480 000 – 2.0 million] | 0.6 [0.4 – 0.9] | 490 000 [300 000 – 750 000] |
| East Asia | 1.1 million [560 000 – 1.8 million] | 290 000 [84 000 – 830 000] | 0.1 [0.1 – 0.2] | 51 000 [25 000 – 86 000] |
| Latin America | 1.7 million [1.3 – 2.2 million] | 240 000 [170 000 – 430 000] | 0.6 [0.5 – 0.8] | 95 000 [73 000 – 120 000] |
| Caribbean | 440 000 [270 000 – 780 000] | 53 000 [27 000 – 140 000] | 2.3 [1.5 – 4.1] | 36 000 [24 000 – 61 000] |
| Eastern Europe & Central Asia | 1.4 million [920 000 – 2.1 million] | 210 000 [110 000 – 480 000] | 0.8 [0.5 – 1.2] | 60 000 [39 000 – 87 000] |
| Western & Central Europe | 610 000 [480 000 – 760 000] | 21 000 [14 000 – 38 000] | 0.3 [0.2 – 0.3] | 6 500 [<8 500] |
| North America | 1.0 million [540 000 – 1.6 million] | 44 000 [16 000 – 120 000] | 0.6 [0.3 – 1.0] | 16 000 [8 400 – 25 000] |
| Oceania | 35 000 [25 000 – 48 000] | 5 000 [2 100 – 13 000] | 0.2 [0.1 - 0.3] | 700 <1 700] |
| TOTAL | 39.4 million [35.9 – 44.3 million] | 4.9 million [4.3 – 6.4 million] | 1.1 % [1.0 - 1.3%] | 3.1 million [2.8 – 3.5 million] |

HIV/AIDS in T&T

| | |
|-------------------------|------------------------|
| Daily in 2004 | 4 new cases of HIV |
| Total HIV (1983 – 2004) | 14536 |
| Male:Female | 60:40 |
| Total AIDS | 5365 |
| Total deaths | 3273 |
| Median age of HIV + | Male – 35, Female – 29 |
| 15 – 24 year olds | 15 % |
| Estimated PLWHA | 3.2 % adults (28,000) |

HIV/AIDS in T&T

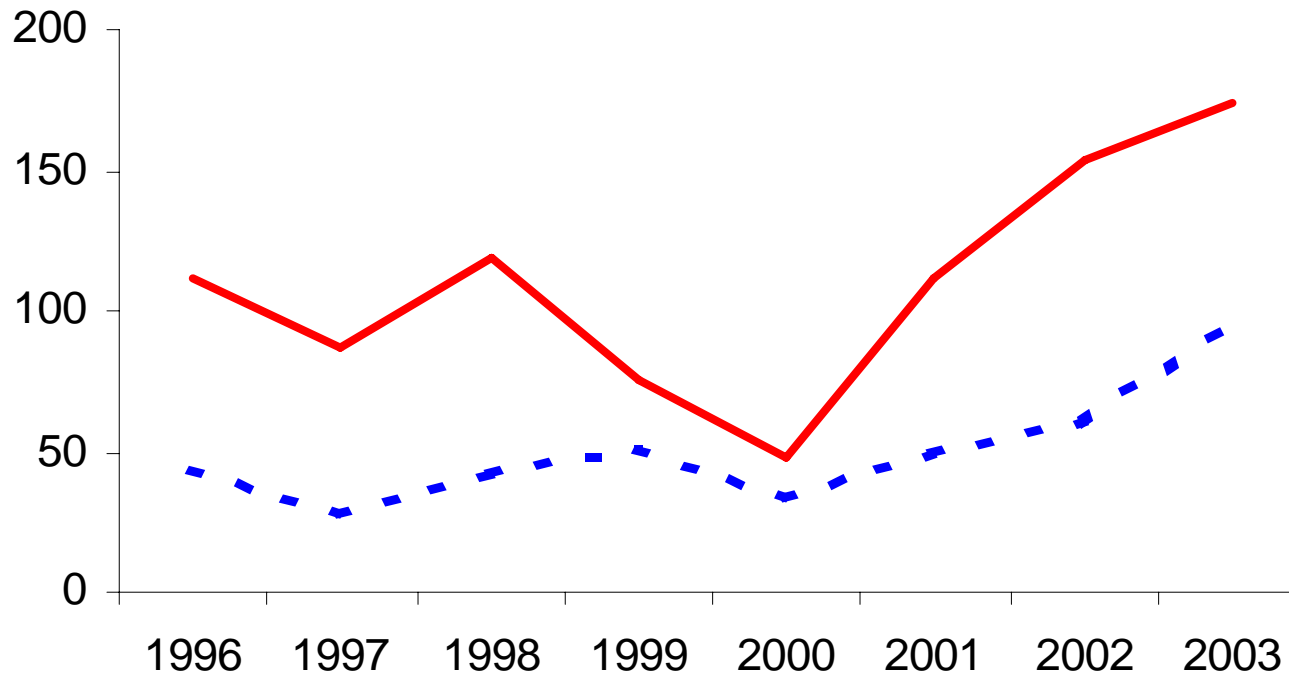
- 70 % of infections in 15-49 age group
- 45 % of new infections occur in females
- In the 15-24 age group, 70 % of the new infections occur in females

HIV/AIDS Surveillance in T & T

- Major reporting units: MRC, POSGH, EWMSC, QPCC/C, Pvt, SFGH, Tobago
- Less than 5% of total HIV/AIDS cases have data on occupation, education, condom usage, partner info, etc
- Data on ethnic origin ?

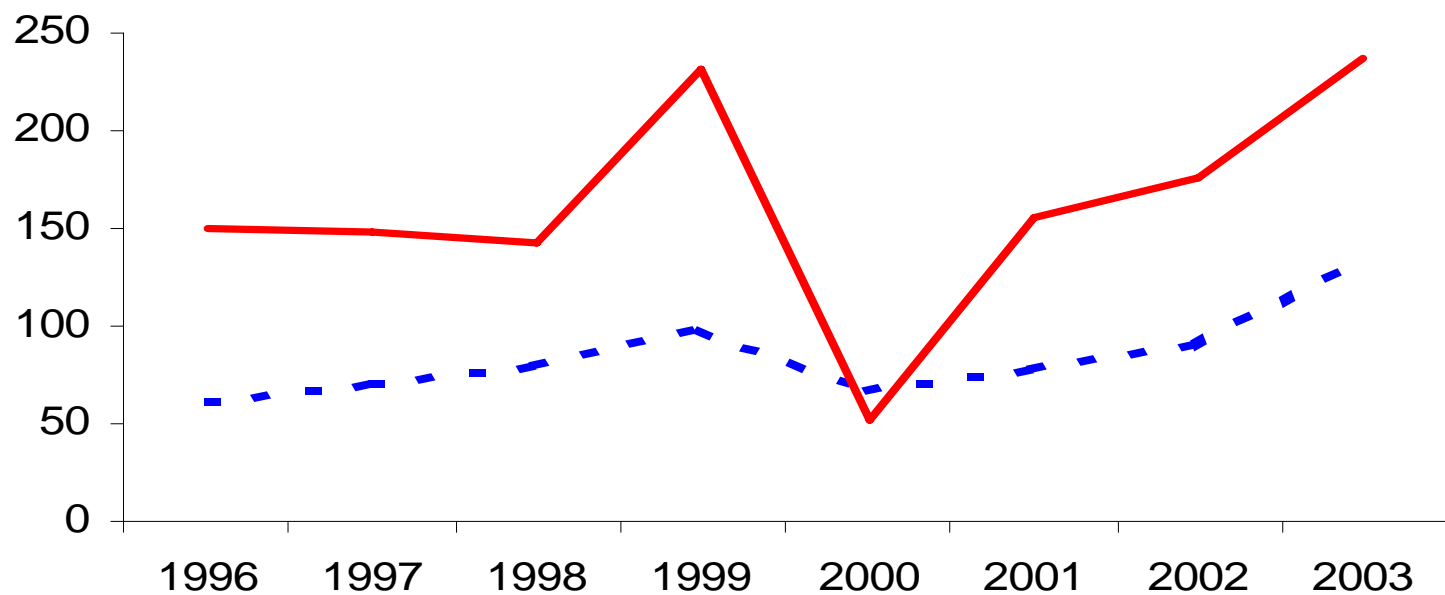
HIV in Age Group: 45-59 Years

45-59 Female 45-59 Male



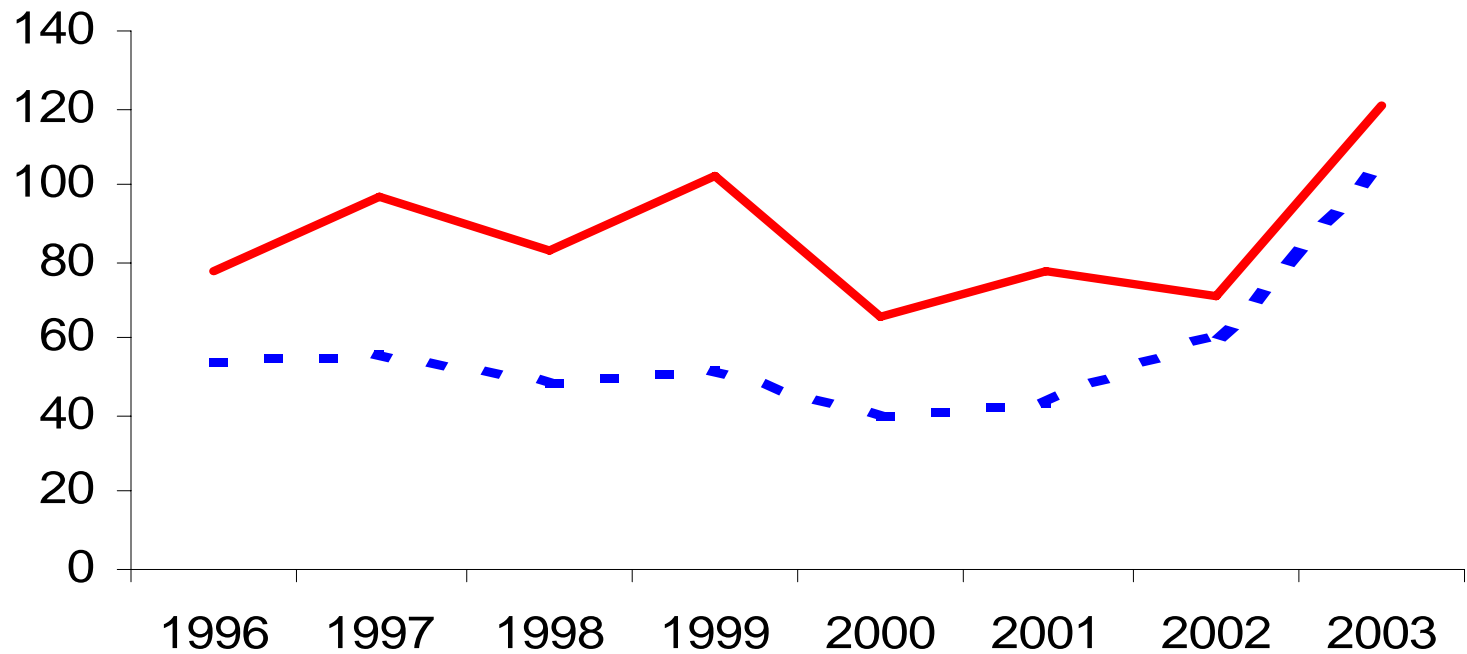
HIV in Age Group: 35-44 Years

--- 35-44 Female — 35-44 Male

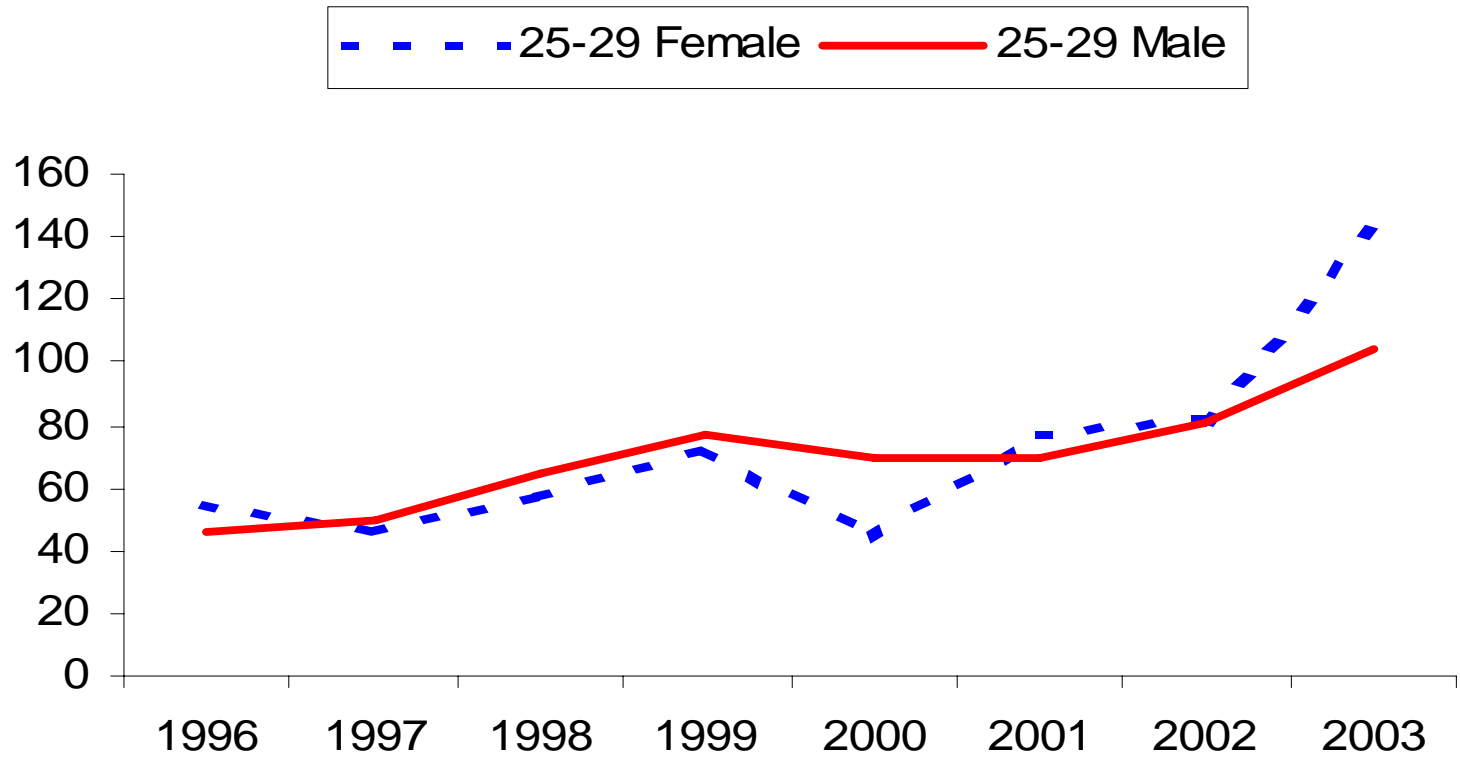


HIV in Age Group: 30-34 Years

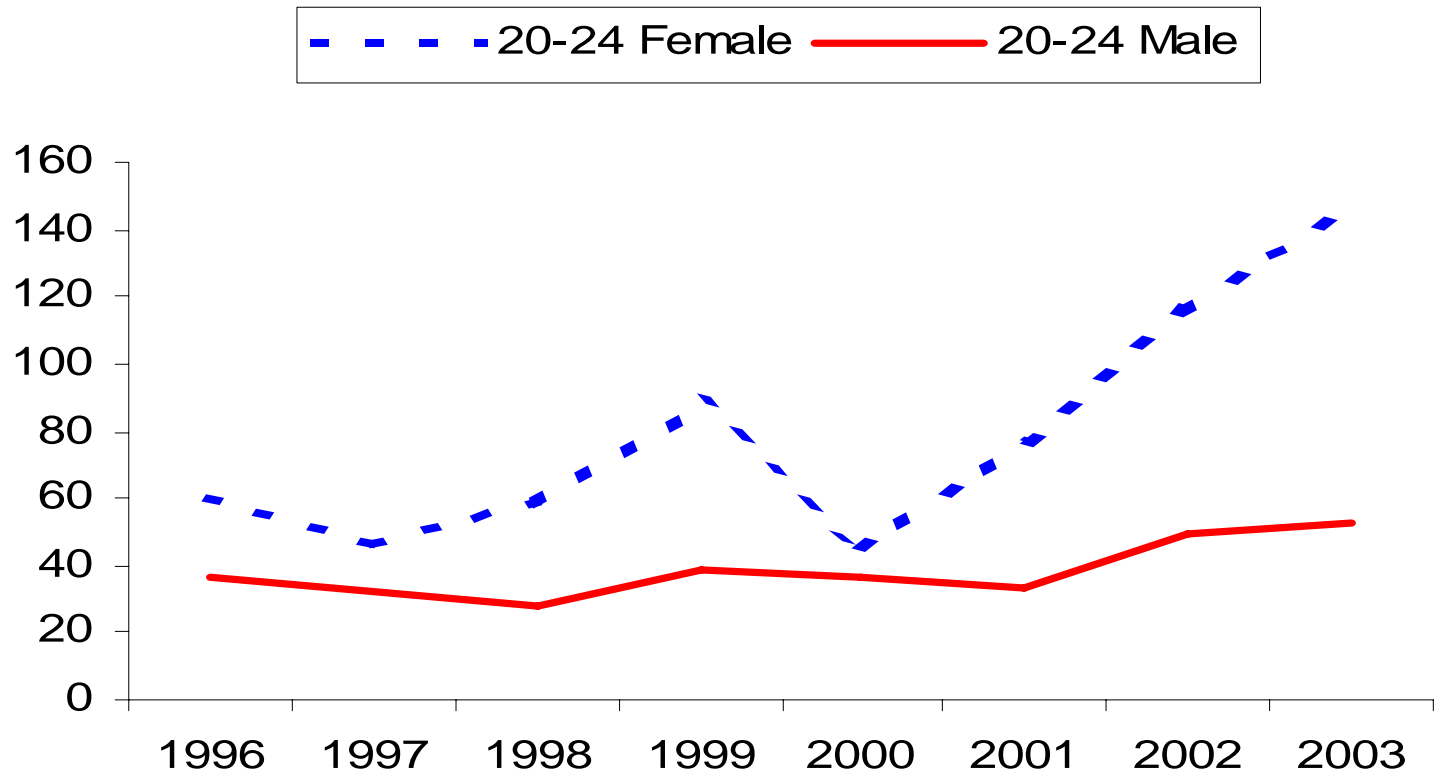
--- 30-34 Female — 30-34 Male



HIV in Age Group: 25-29 Years

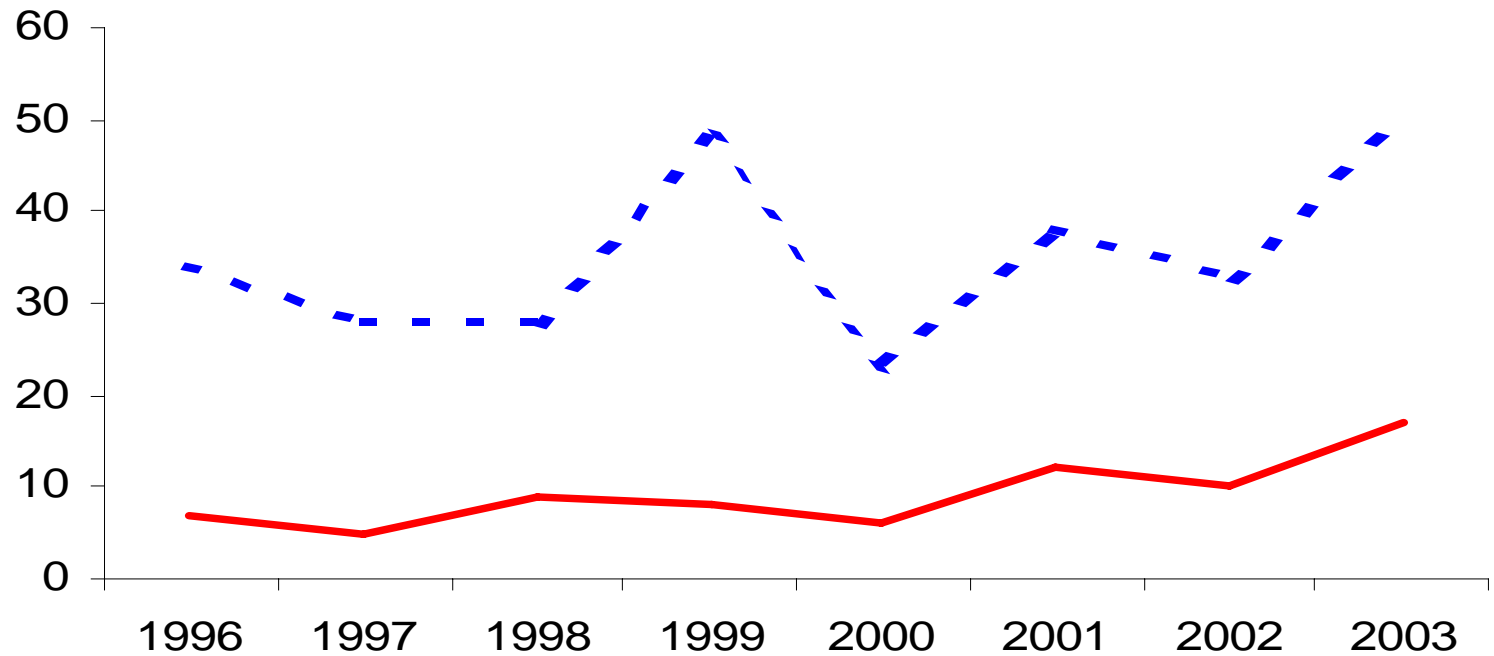


HIV in Age Group: 20-24 Years

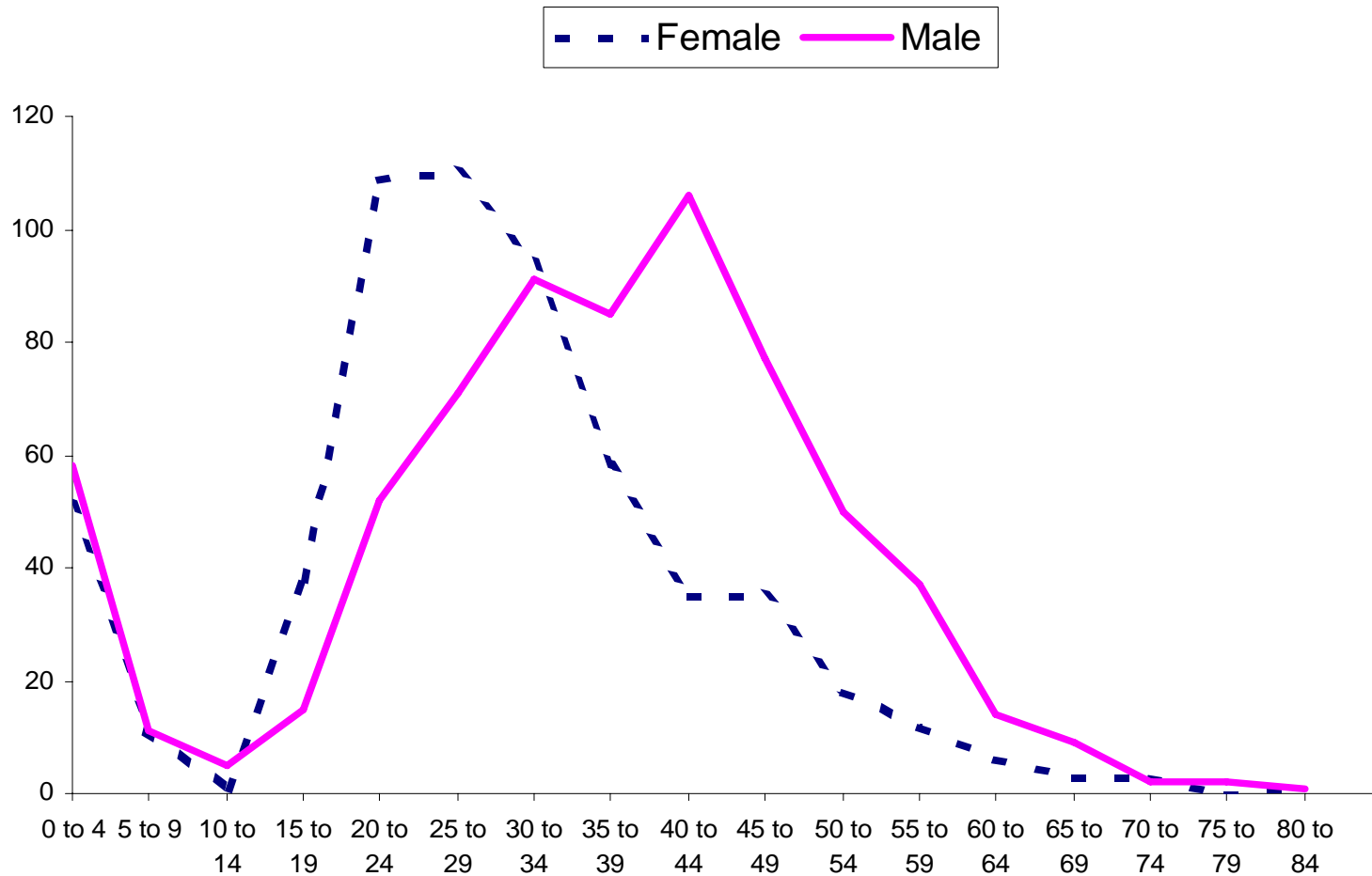


HIV in Age Group: 15-19 Years

15-19 Female 15-19 Male

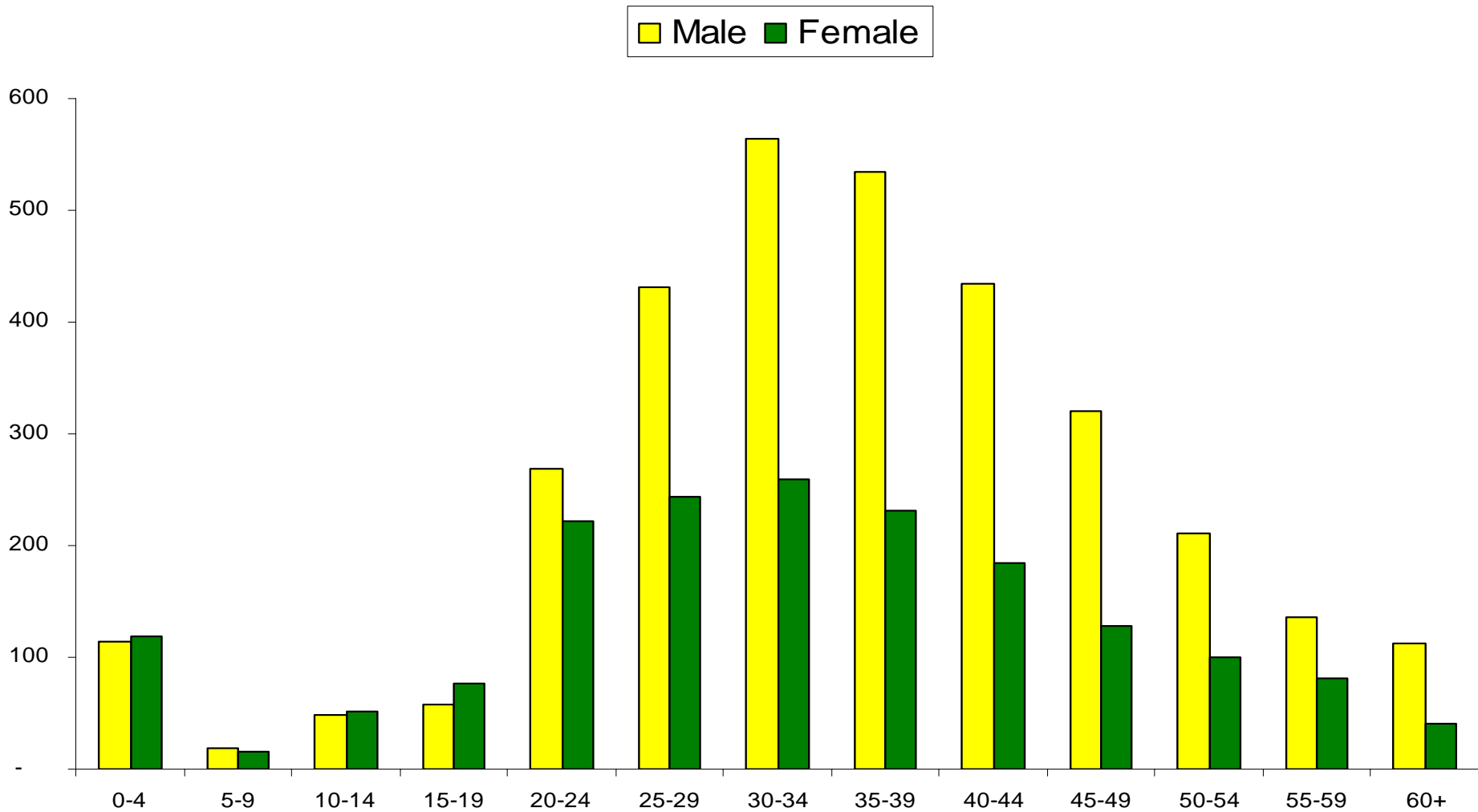


HIV positive in 2004, by age & sex



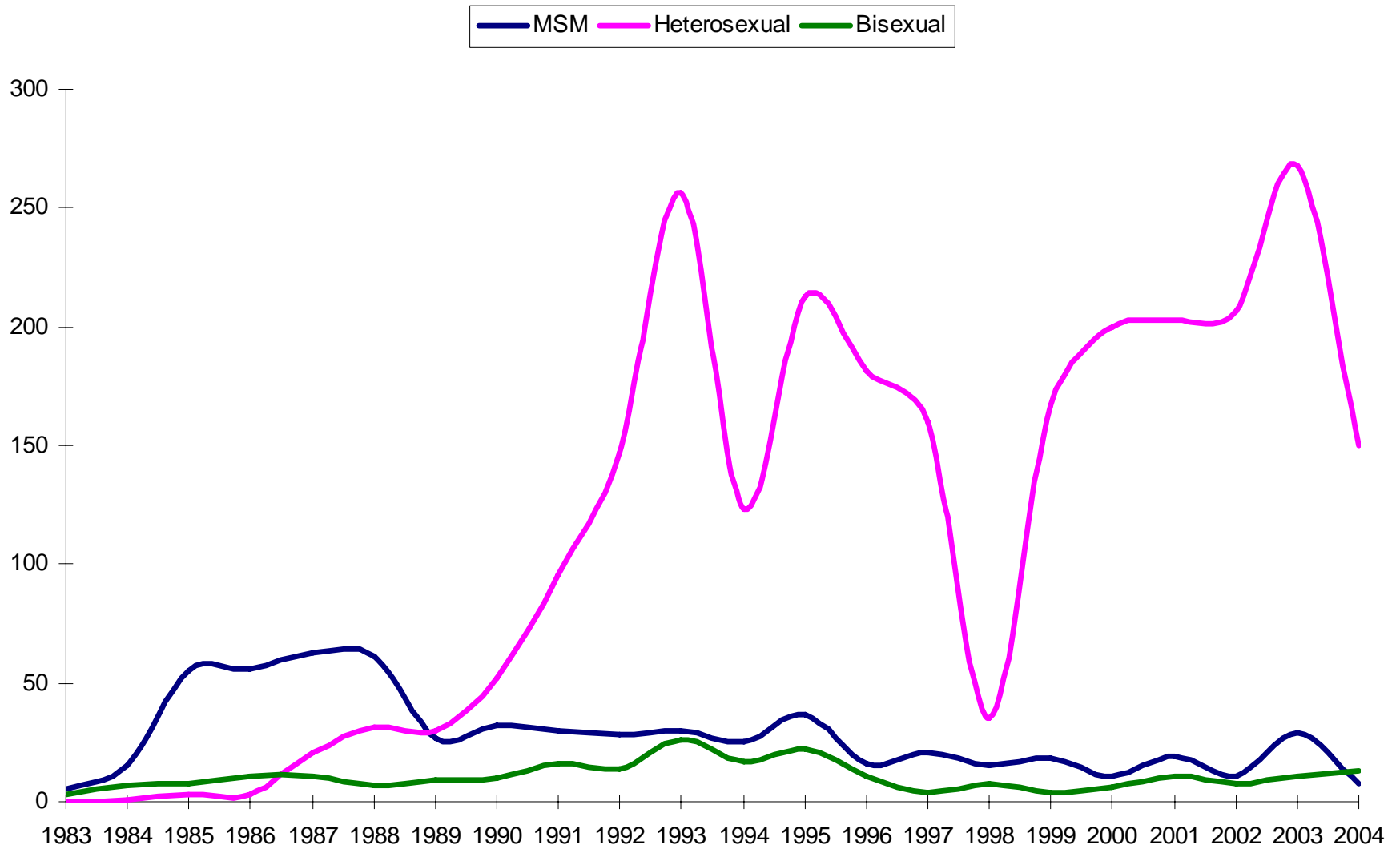
Dr Nilesh Buddha, NSU, MoH, T&T

Cumulative AIDS cases, by age & sex (1983 - 2003)



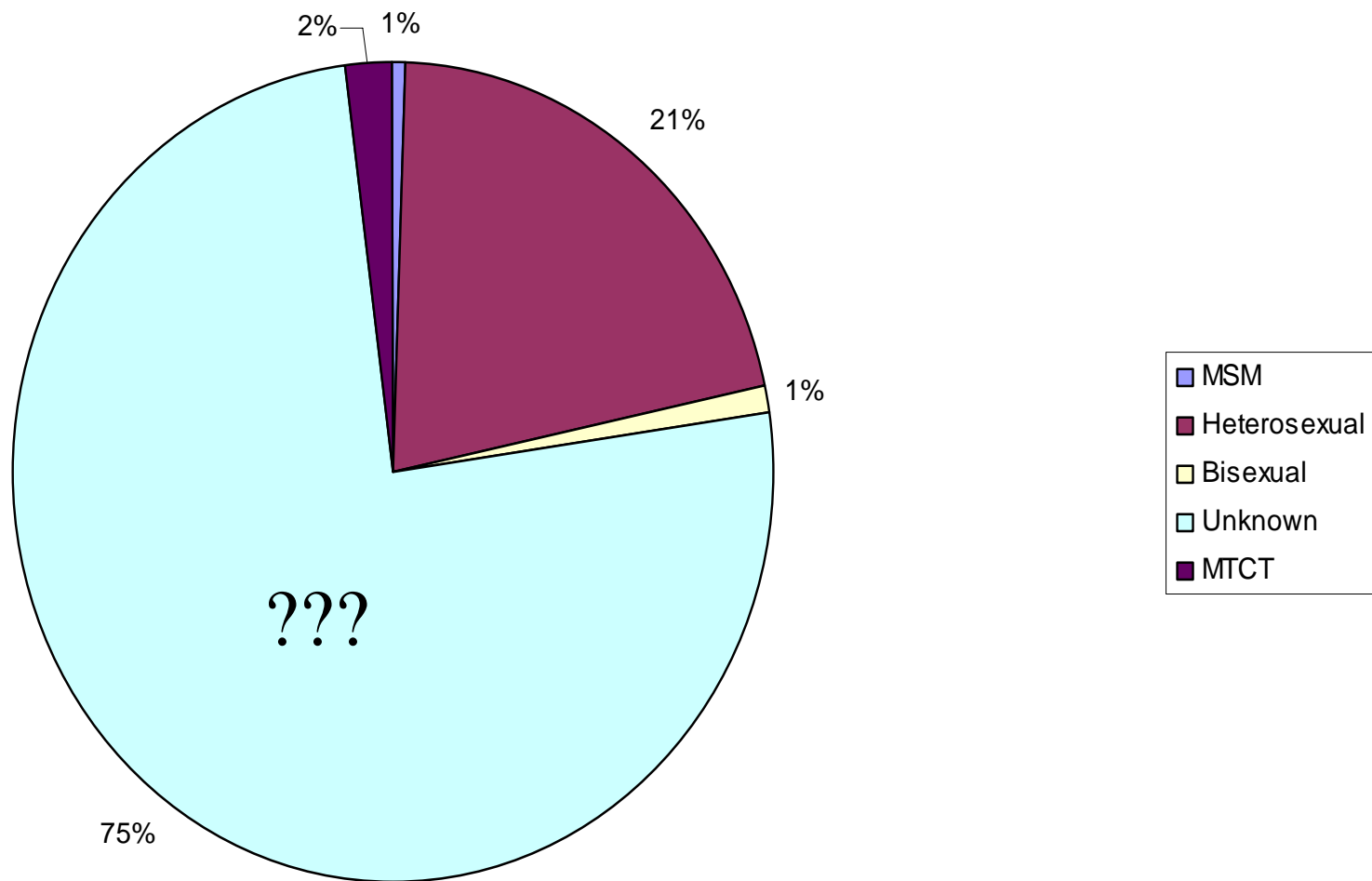
Dr Nilesh Buddha, NSU, MoH, T&T

Male Partner - all HIV Positive



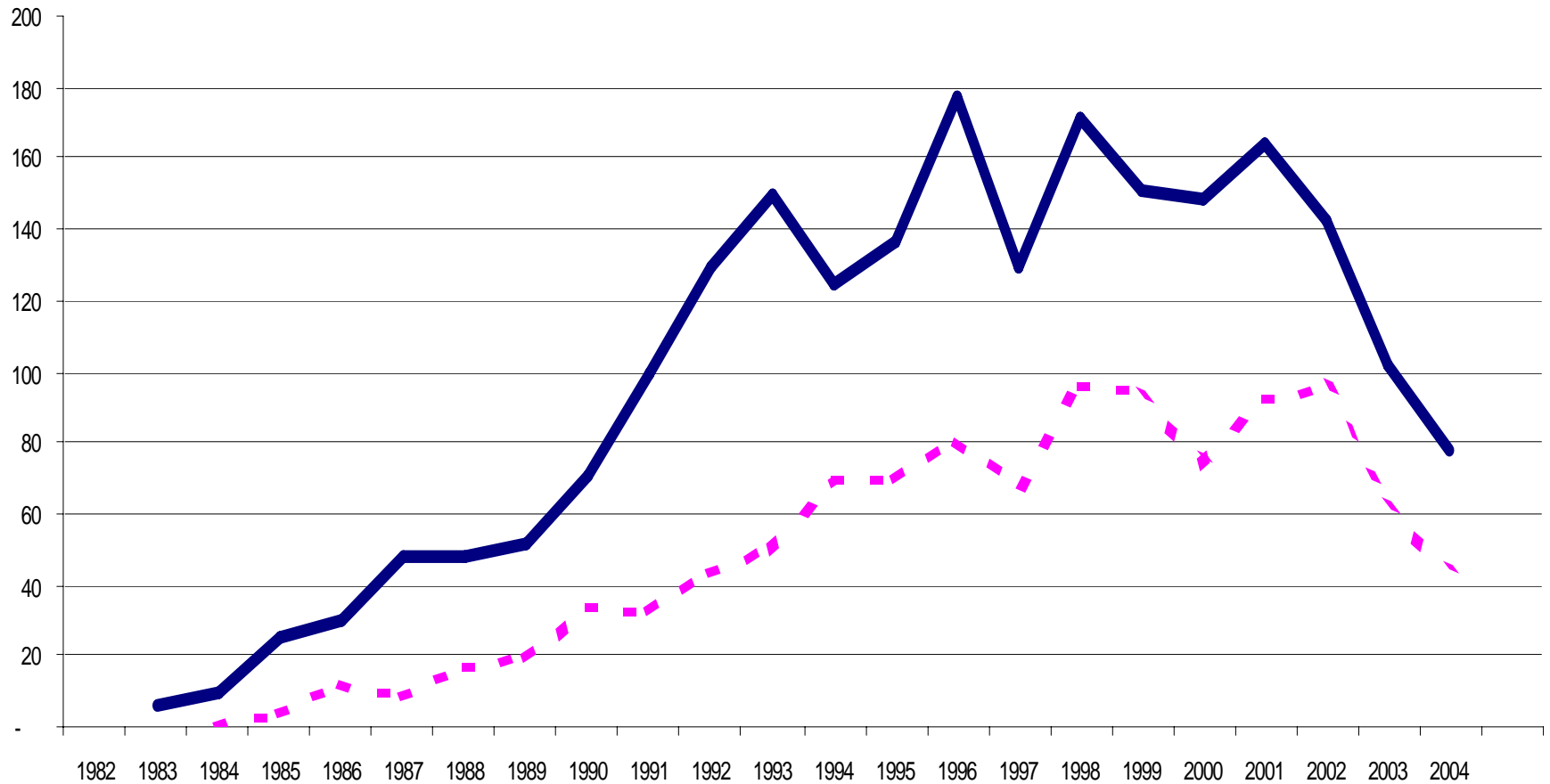
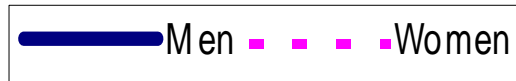
Dr Nilesh Buddha, NSU, MoH, T&T

HIV Positive Exposure Category 2004



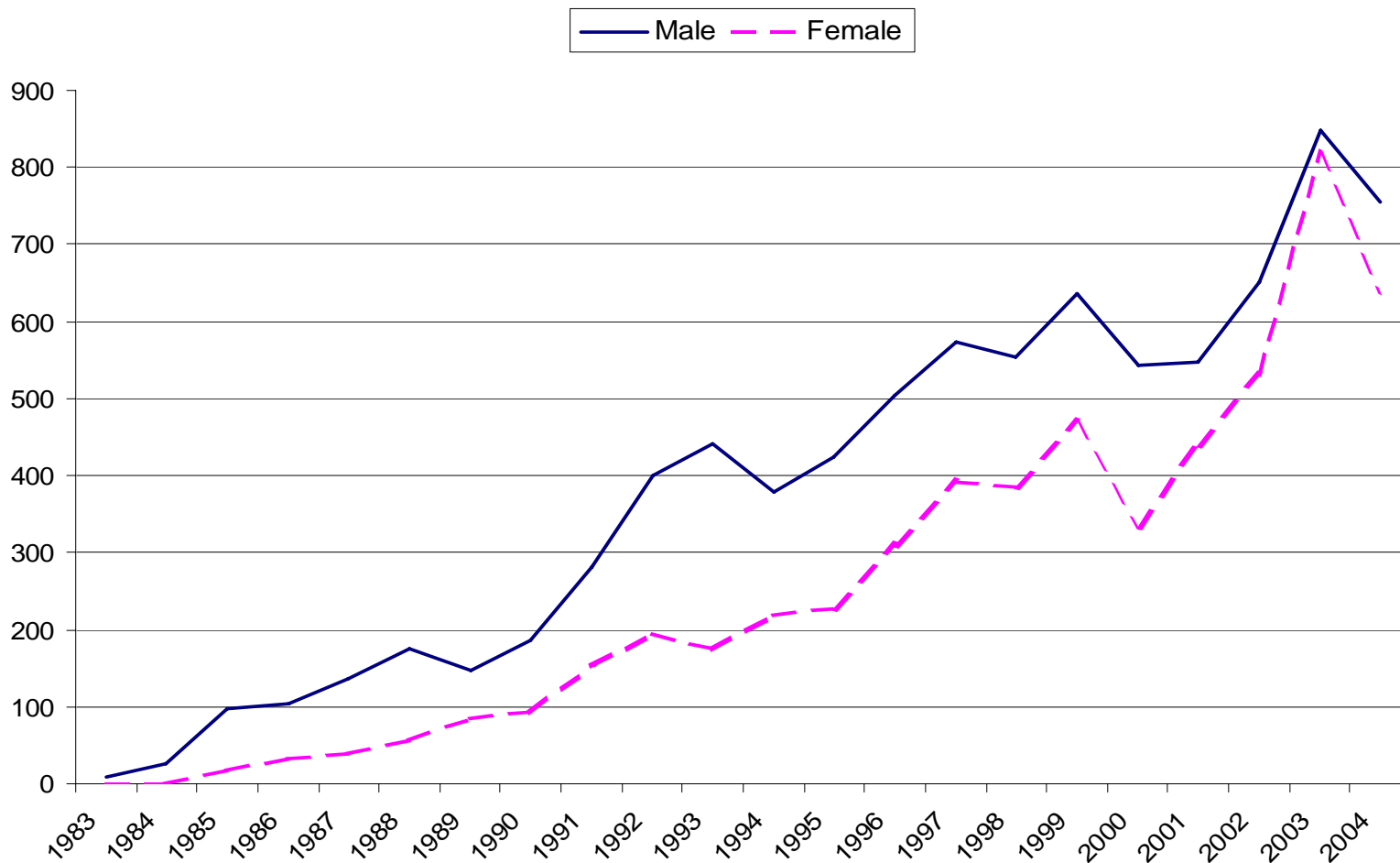
Dr Nilesh Buddha, NSU, MoH, T&T

AIDS Deaths by Year



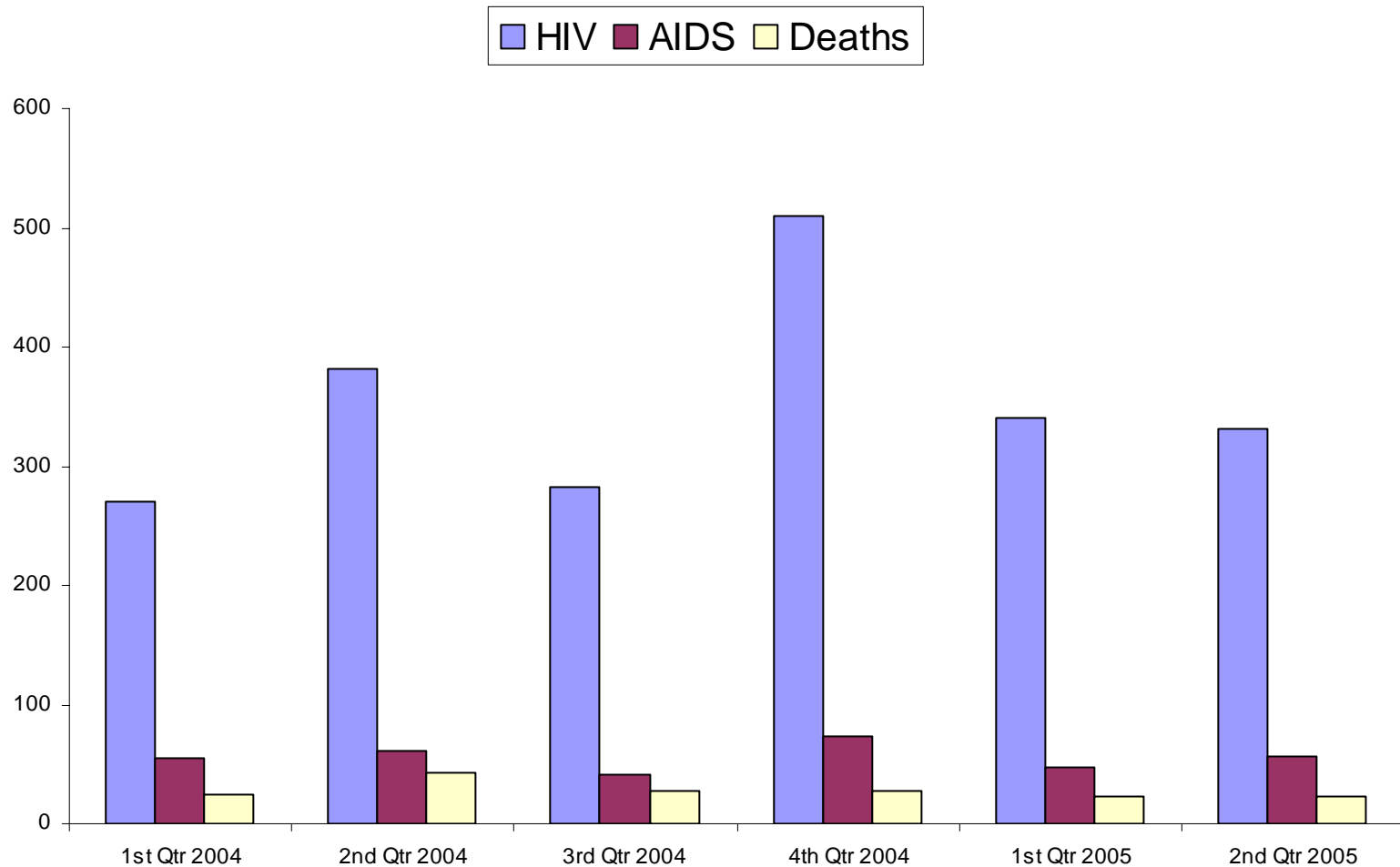
Dr Nilesh Buddha, NSU, MoH, T&T

New cases of HIV per year (1983-2004)



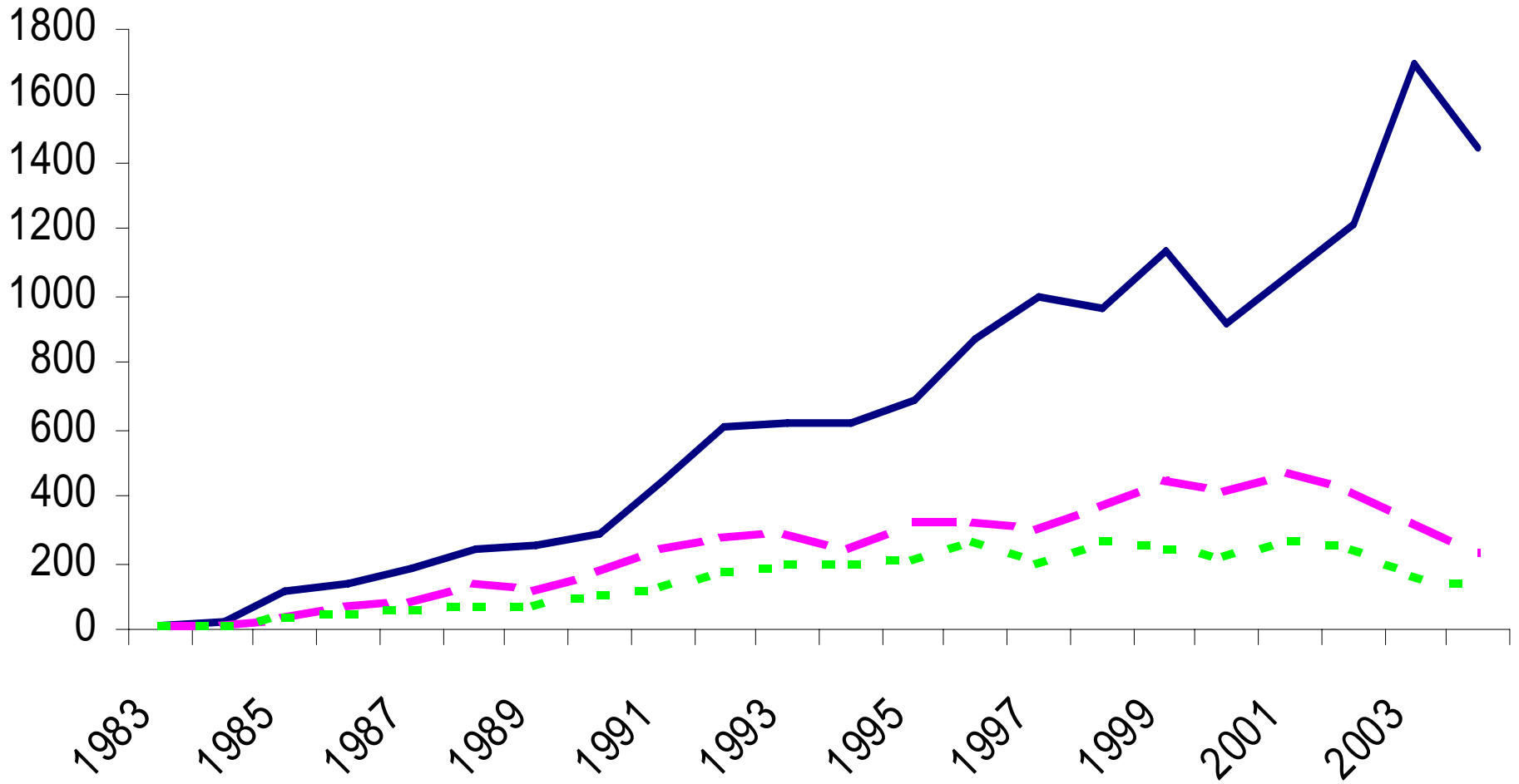
Dr Nilesh Buddha, NSU, MoH, T&T

NSU Quarterly Reports



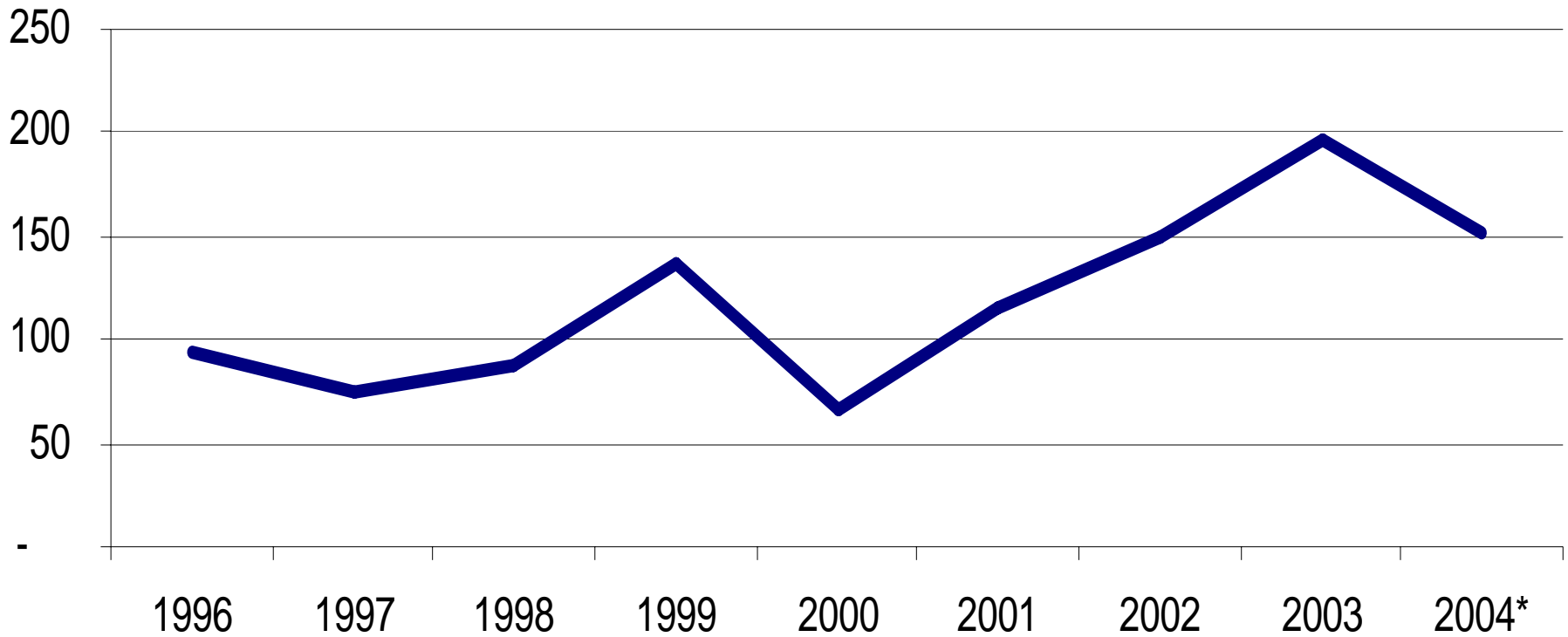
Dr Nilesh Buddha, NSU, MoH, T&T

Incidence



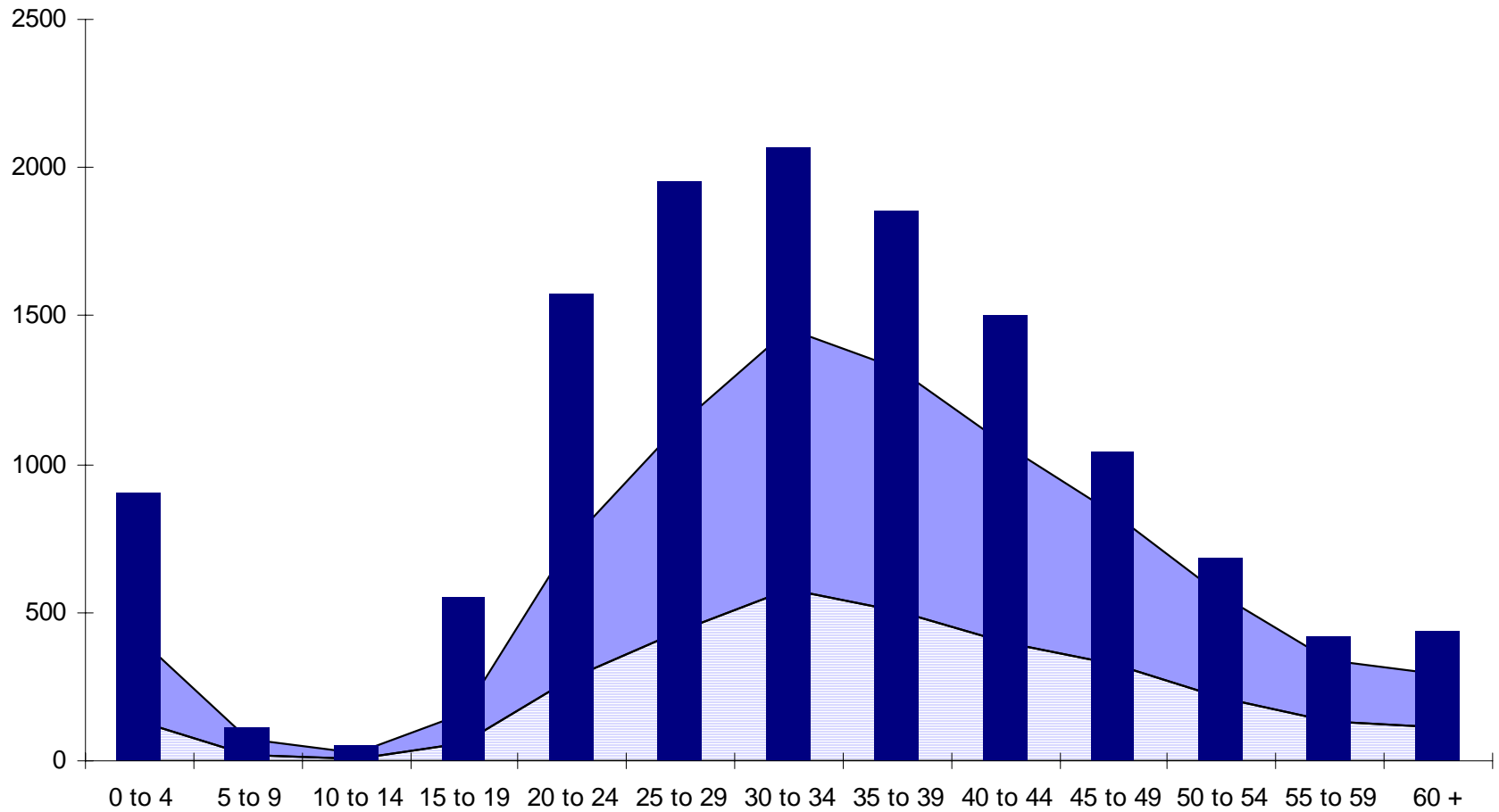
Recently Acquired HIV Infection Trend

— Women, 15-24 Years of Age



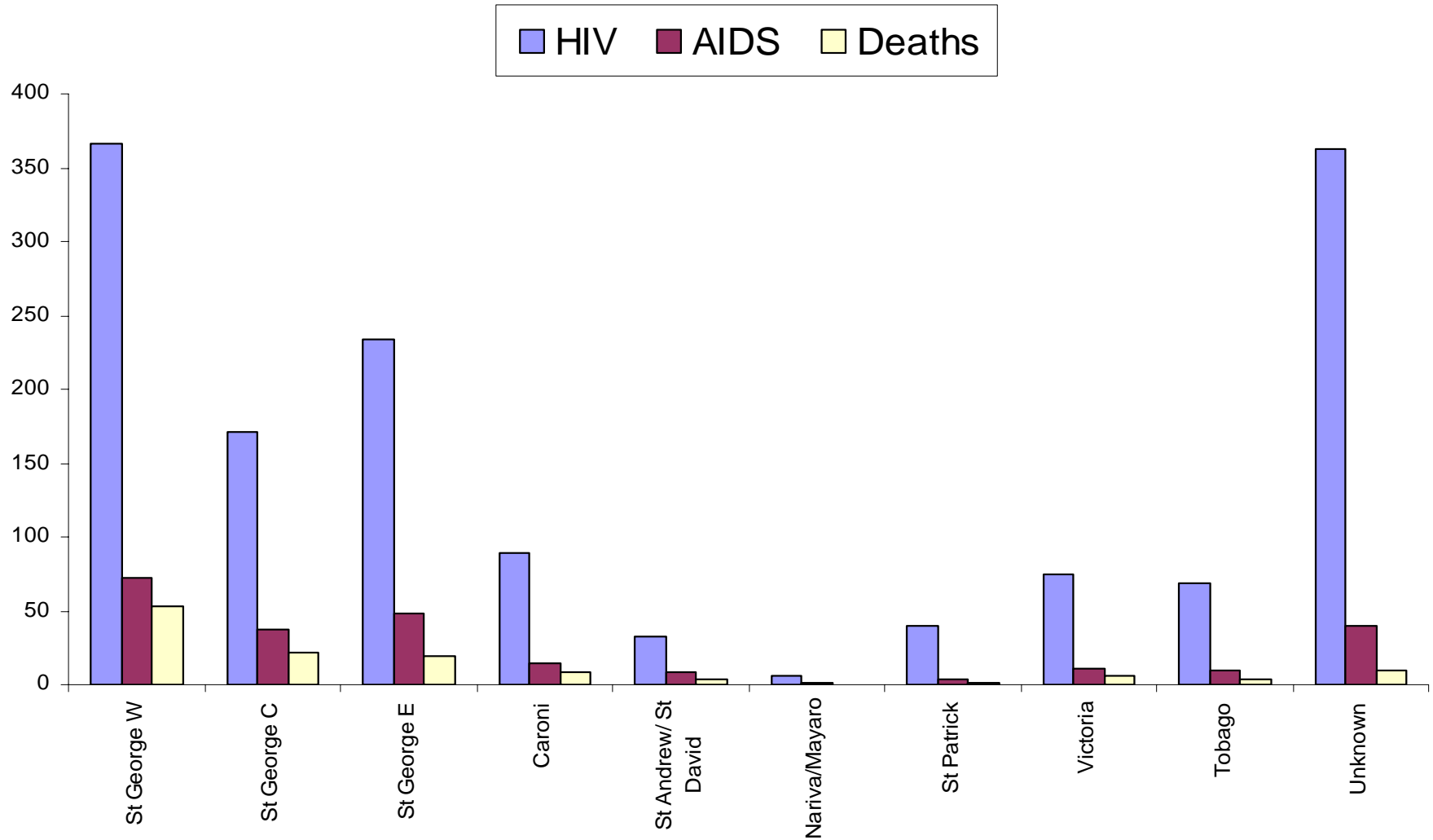
Cumulative (1983 - 2004), by age

□ AIDS deaths ■ AIDS cases ■ HIV positive

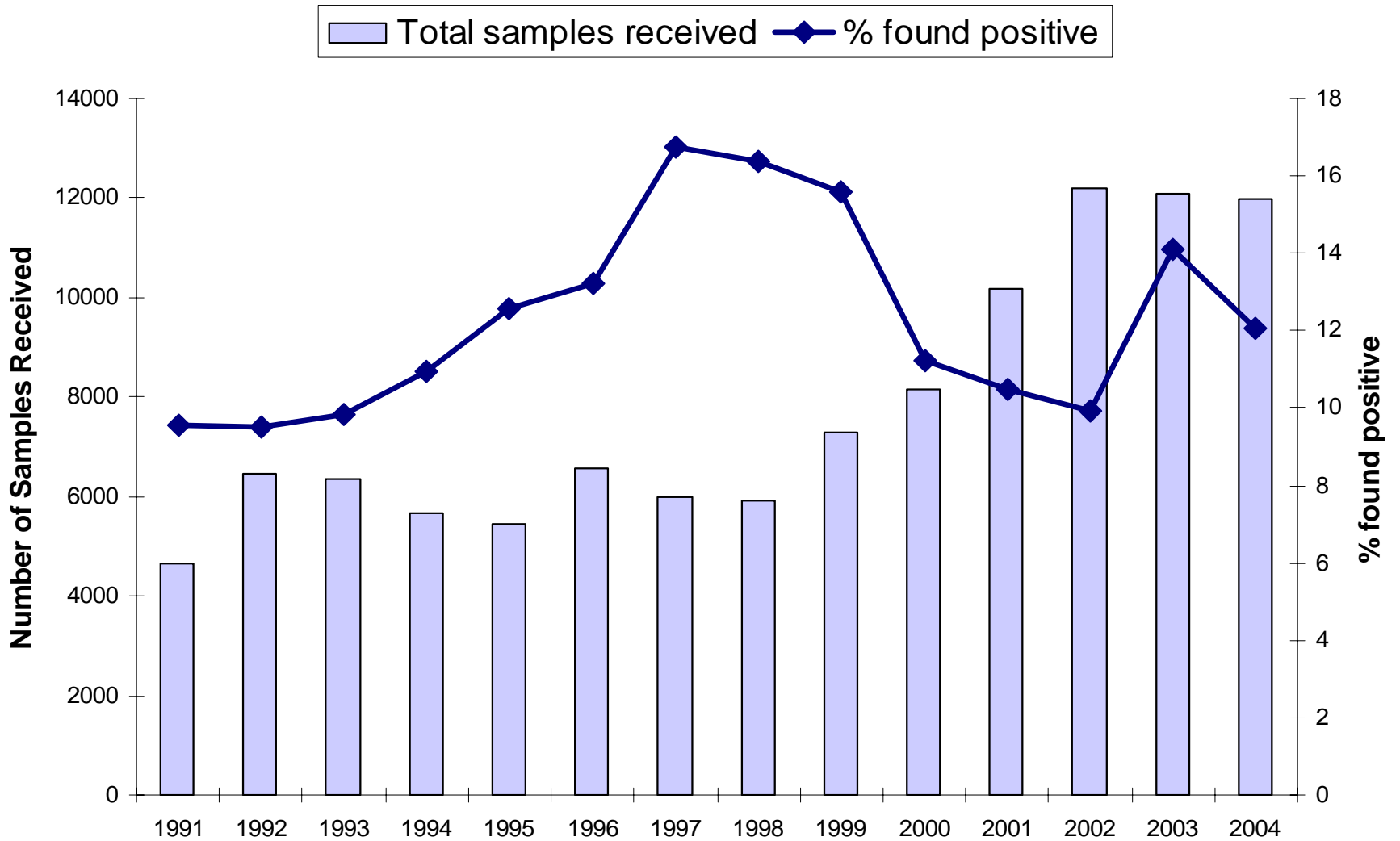


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Counti-wise Incidence, 2004

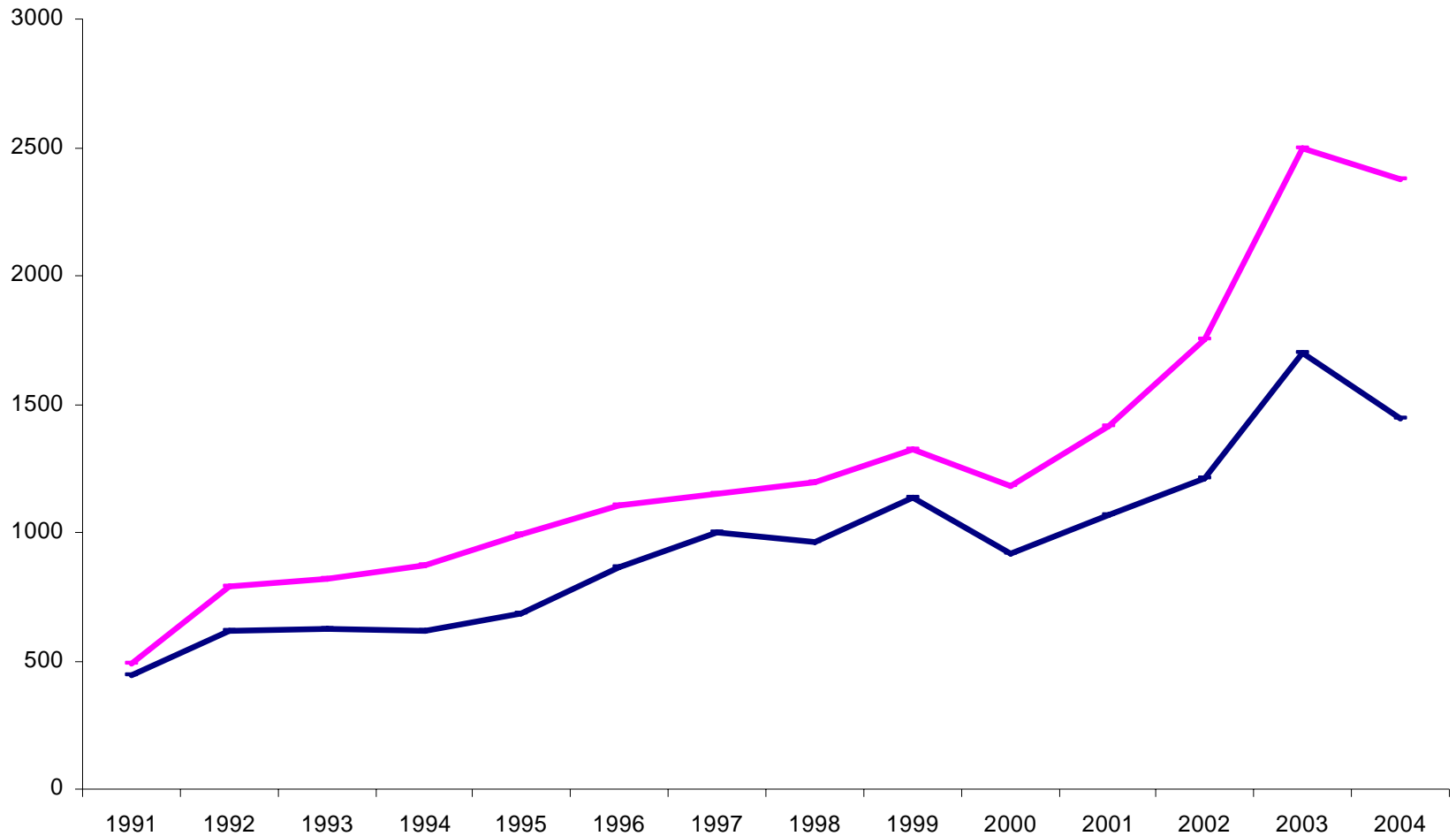
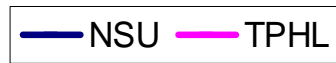


HIV Positivity rate



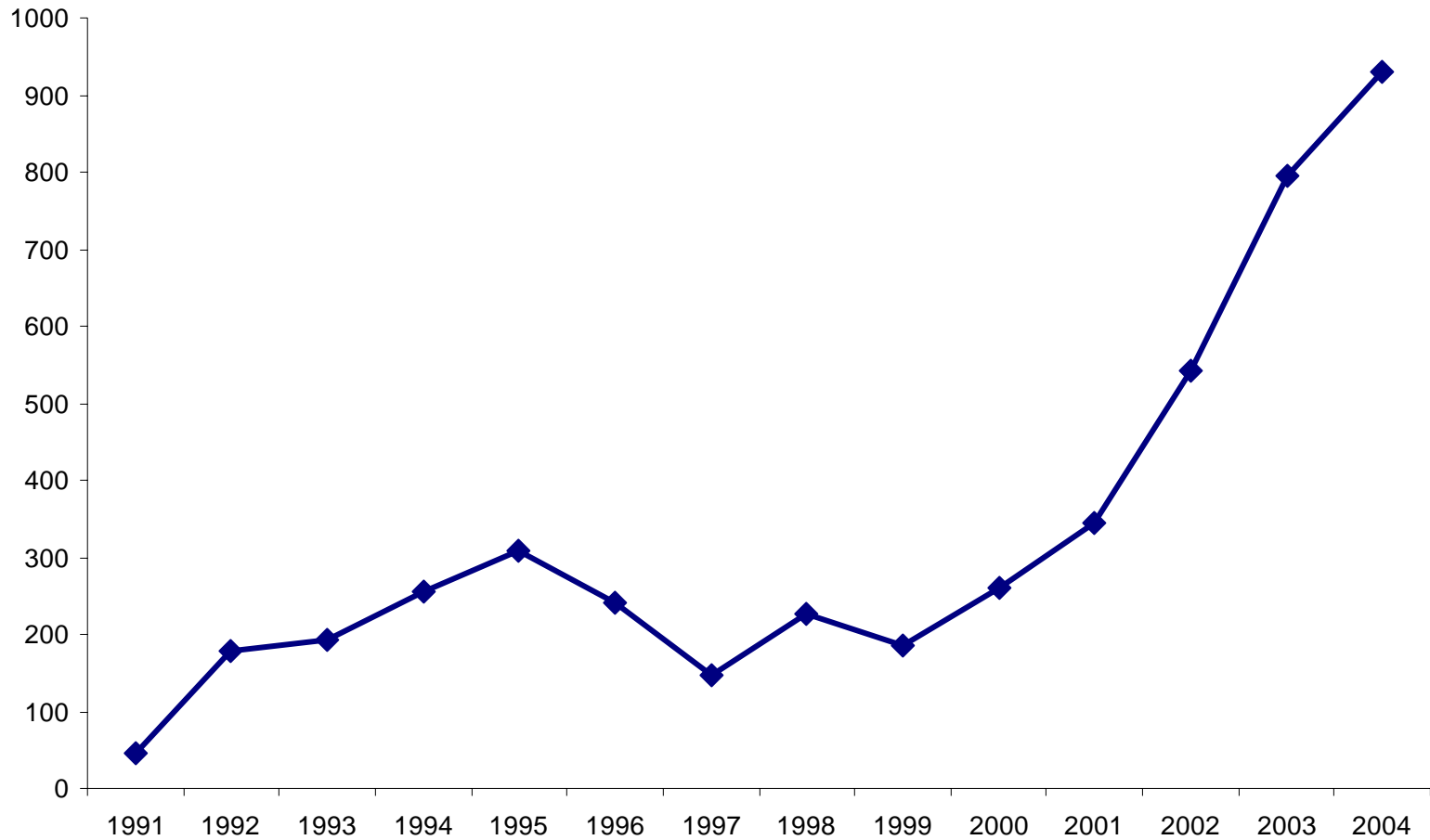
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HIV Positive



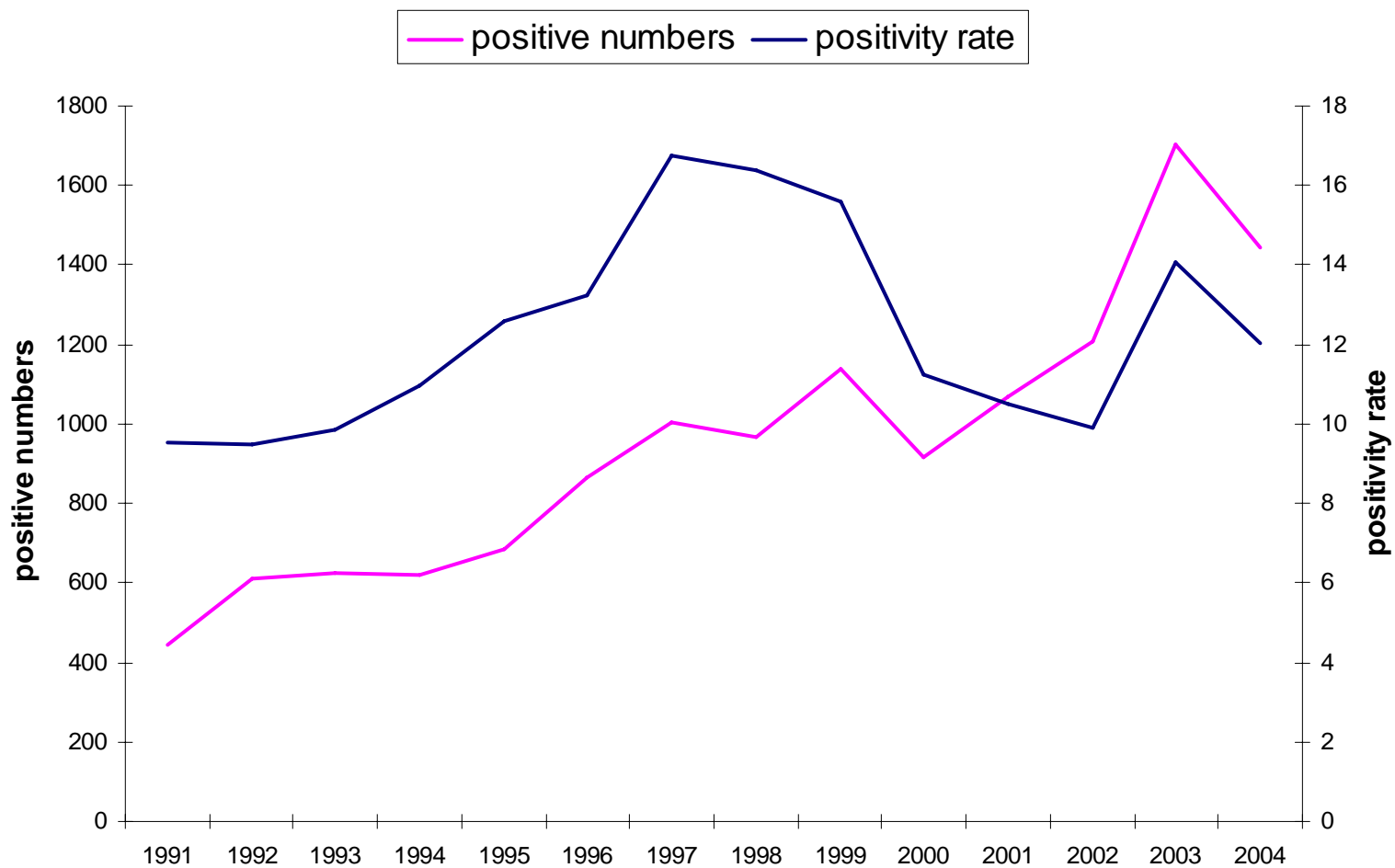
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HIV Positive Duplicates identified at NSU



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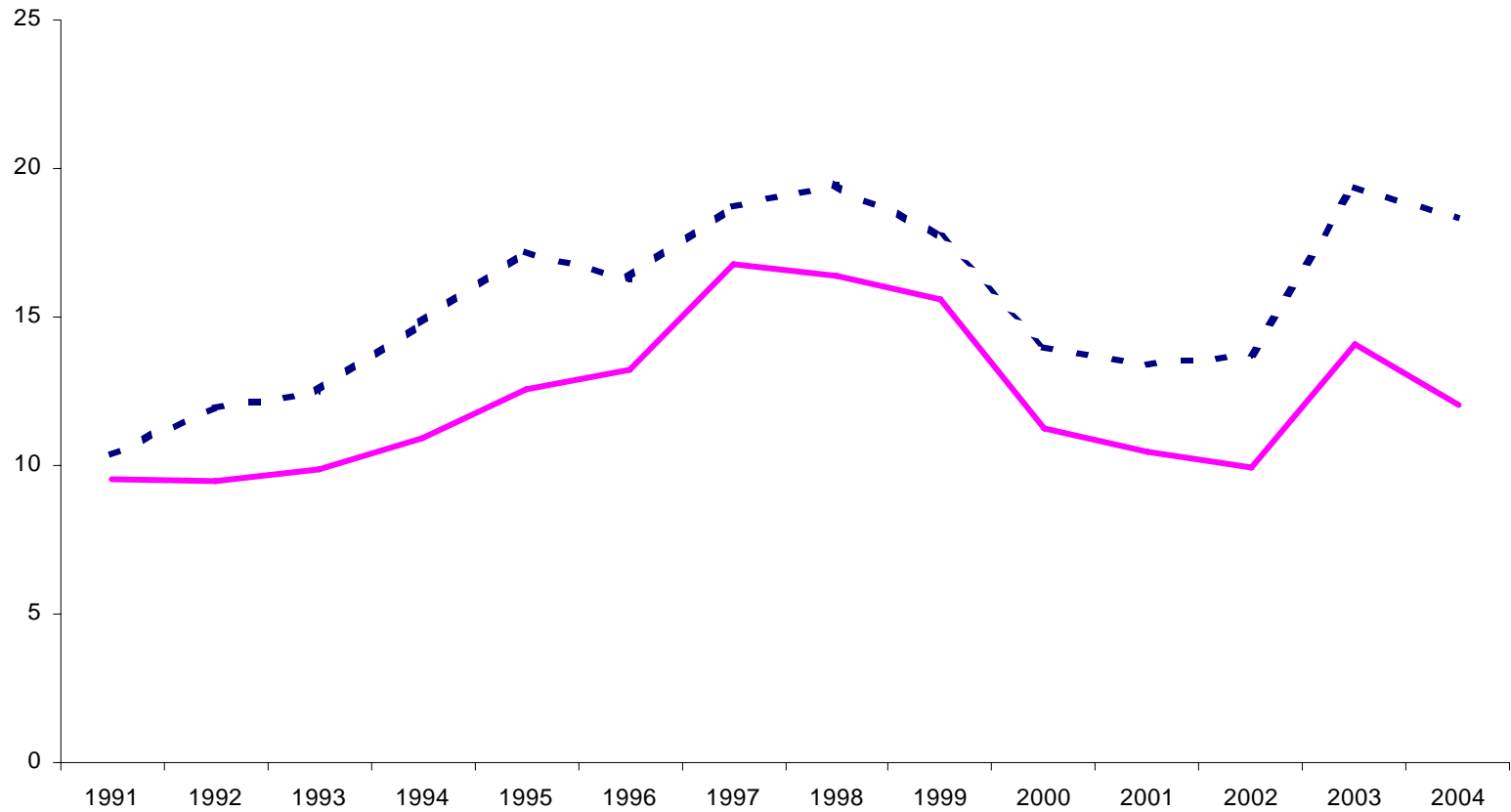
HIV positive



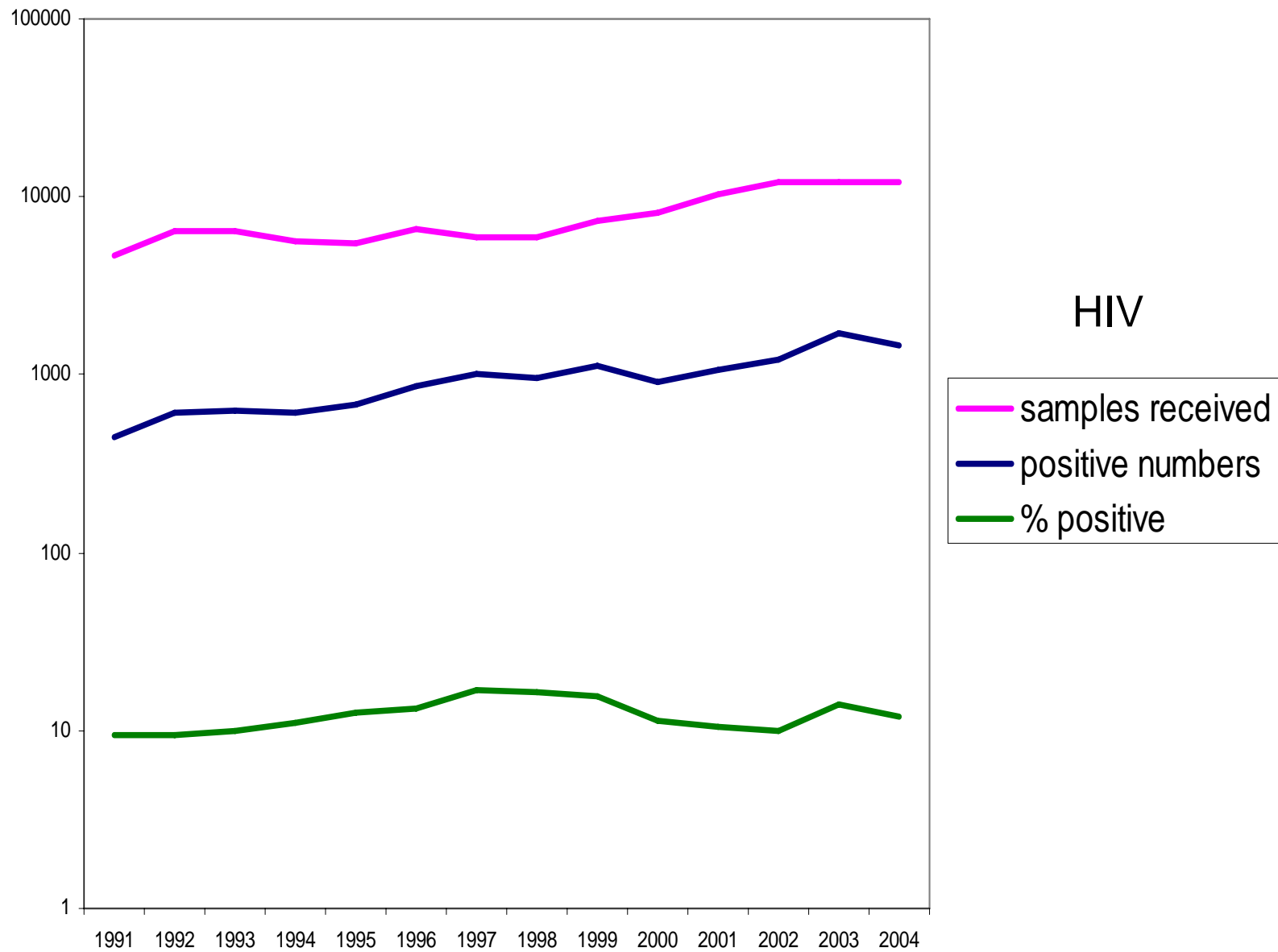
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Positivity Rates
(% found positive among total samples received at TPHL)

- - - Duplicates included — Duplicates excluded



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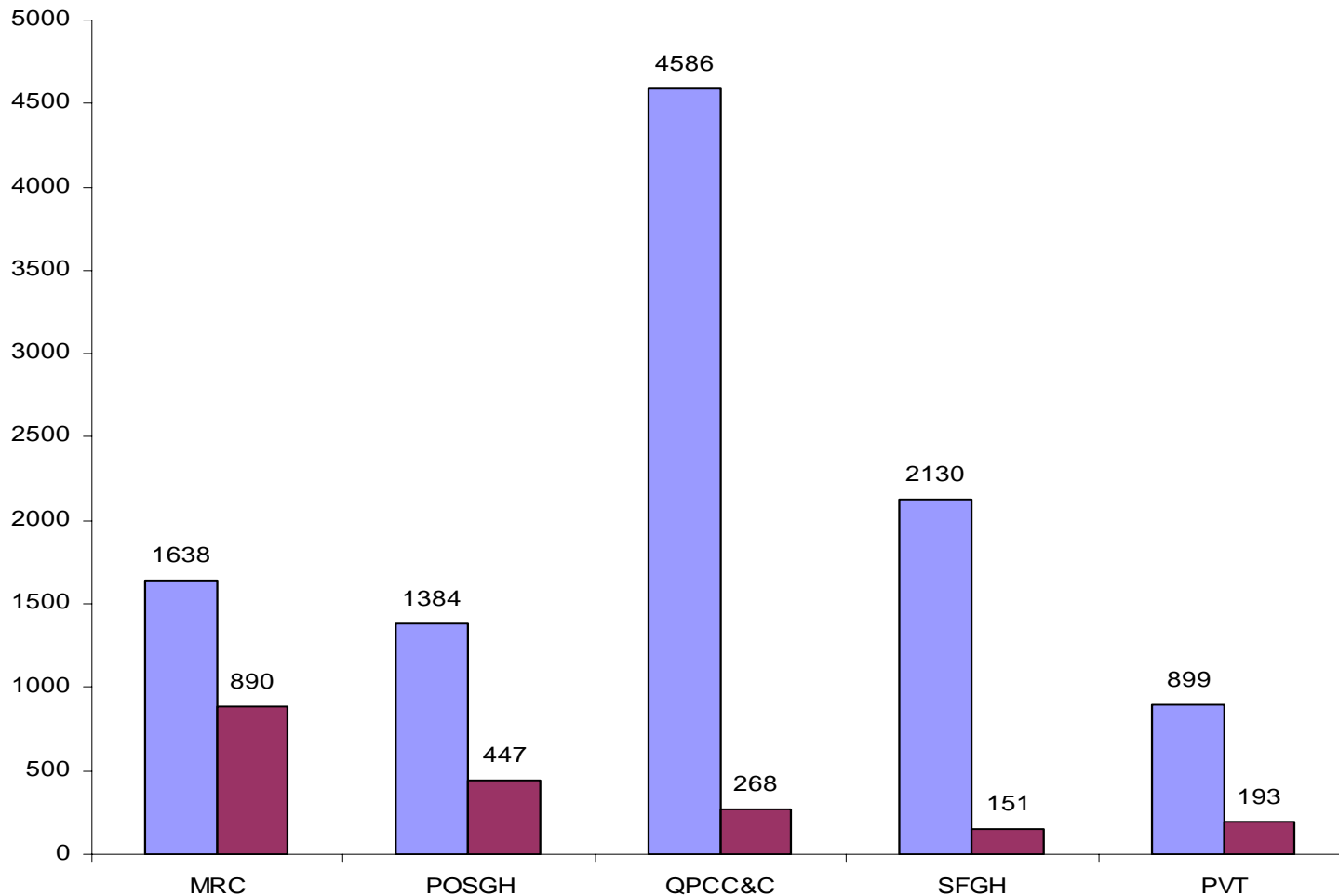


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2004, Major Providers

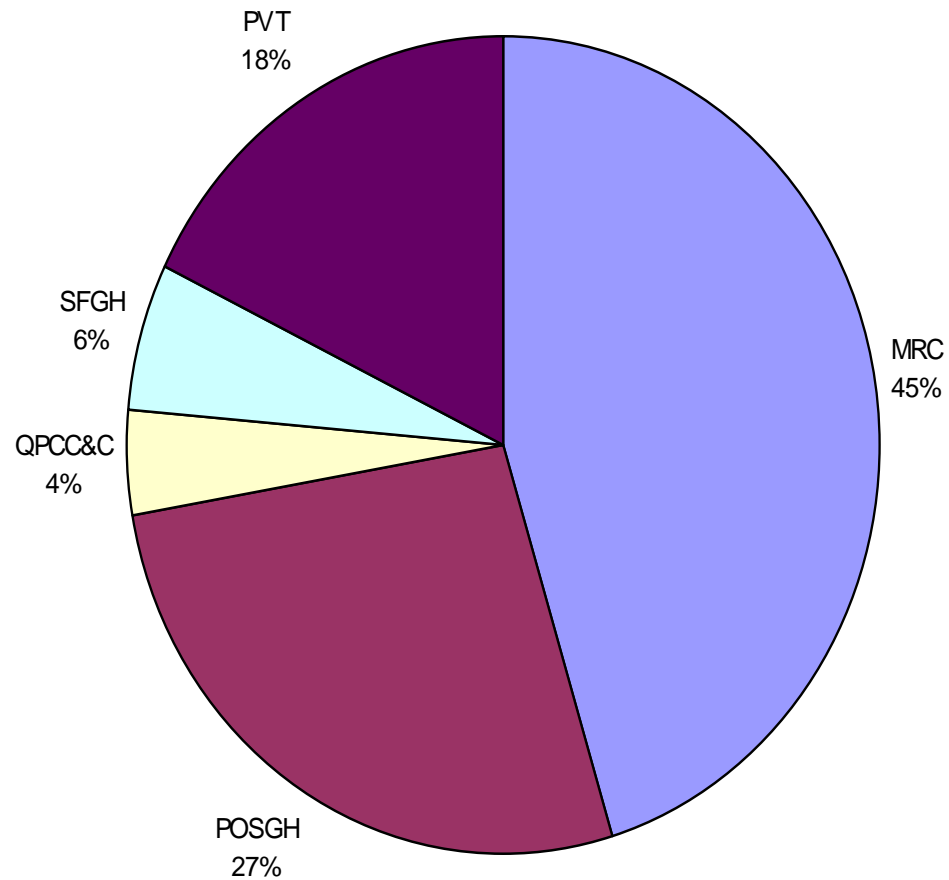
(more than 80% of all tests performed & positive tests)

■ Samples sent for HIV test ■ Samples found positive

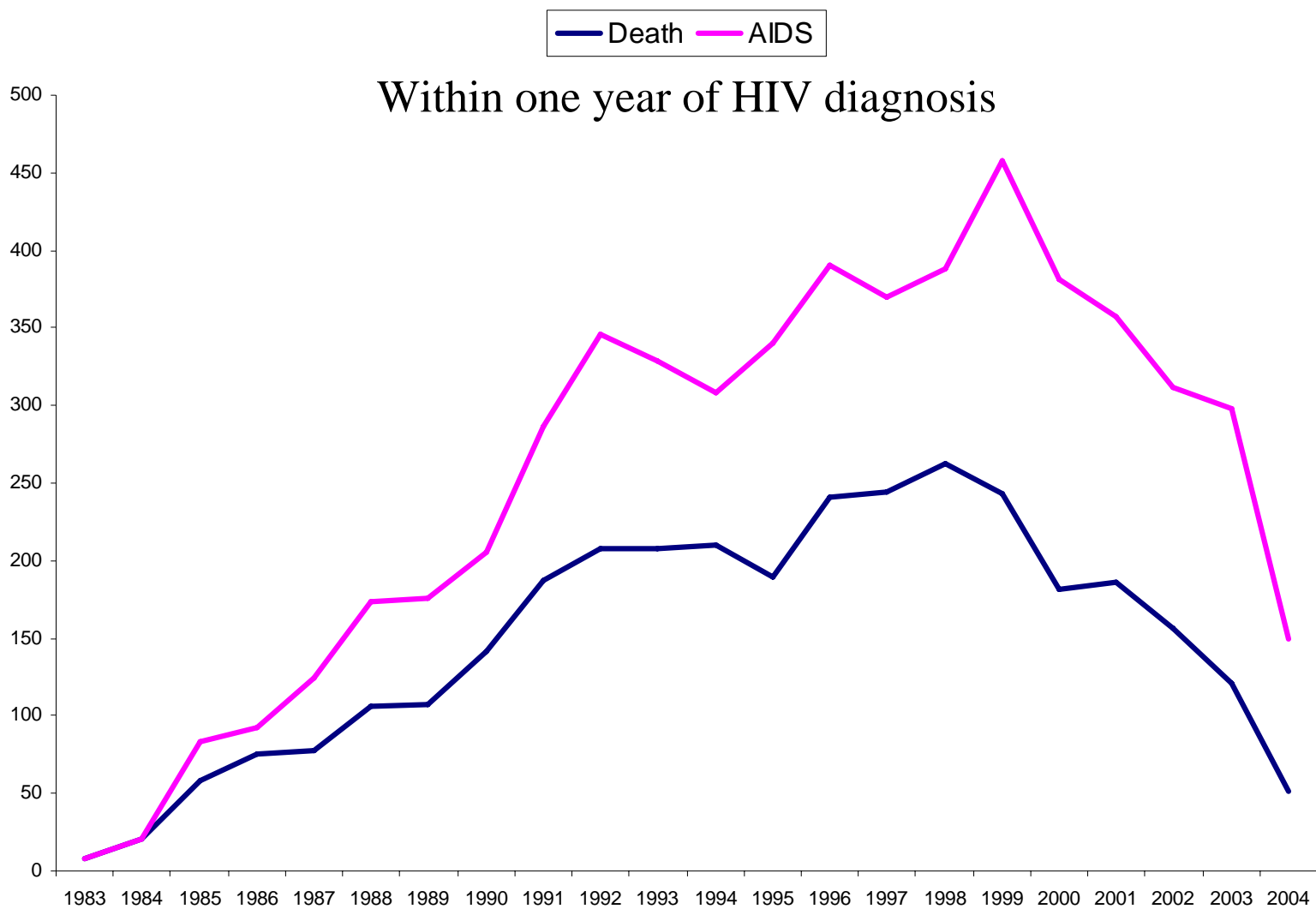


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% positive of total samples
sent to TPHL for HIV testing in 2004

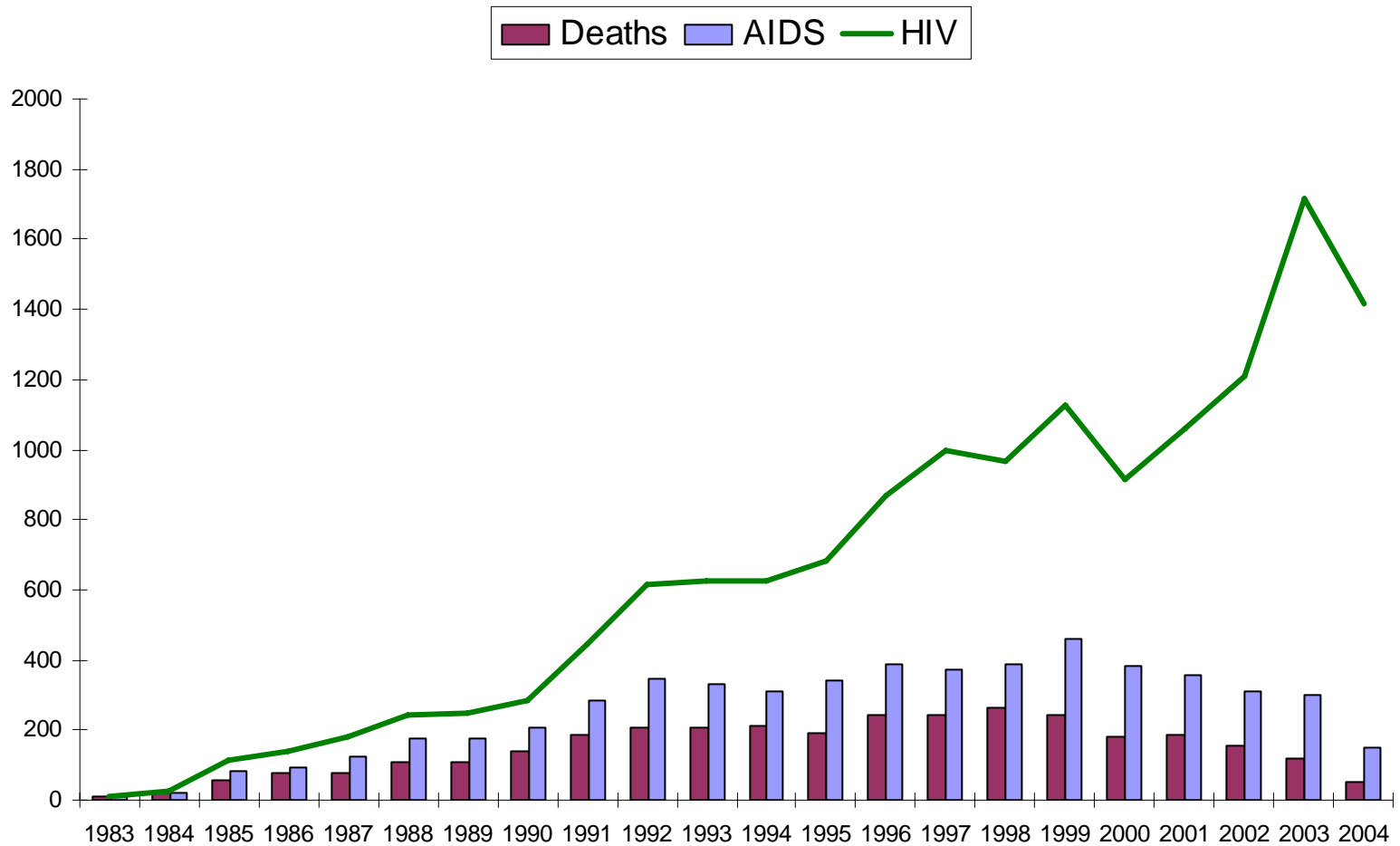


Total >80% of all positive in 2004



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Incidence (1983 - 2004)

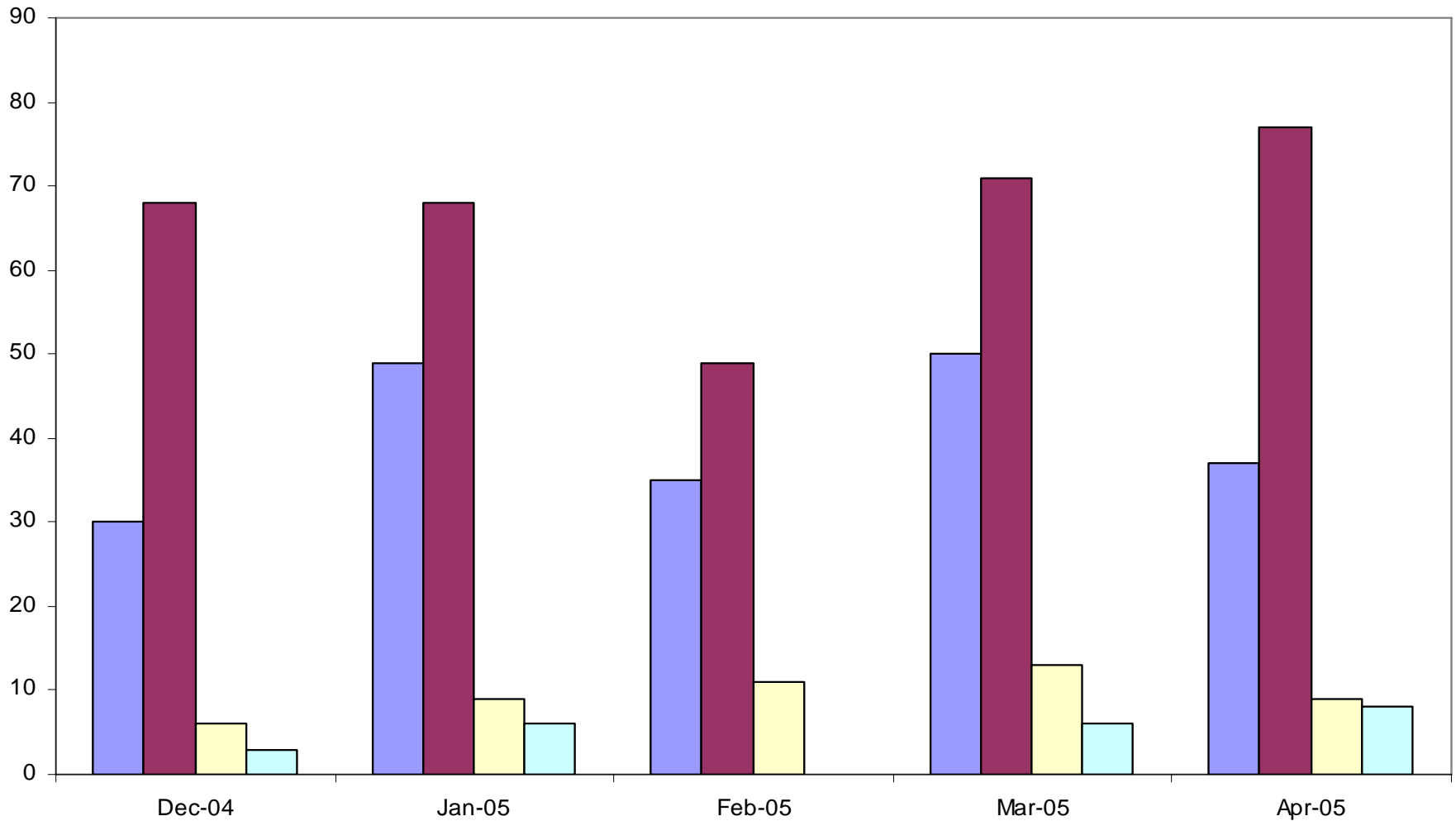


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Monthly HIV/AIDS Admissions in 4 Public Hospitals

Data source: Active Surveillance
Register, NSU

■ SFGH ■ POSGH ■ EWMSC ■ SGH



Dr Nilesh Buddha, NSU, MoH, T&T

Features

- Principle mode of transmission – Heterosexual, multiple sexual partners, unsafe sex
- Principle age at transmission – young females, adult males in all age groups
- Young men missed-out in VCT – remain continued source of infection
- Condom usage ? Substance abuse ? Ethnicity ?
- Occupation, education, socio-economic status ?
- ARV works, more resources will be required for sustained Care & Treatment

Features (contd)

- HIV/AIDS scenario at very crucial stage in 2005; sustained efforts in Prevention, Care & Treatment will yield very good returns
- Proximal causes – risky behaviours
- Solution – behavioral change communication (population-wide & high-risk targeted)
- Underlying causes – socio-economic (deprived, poor, disrupted families, uneducated, unemployed)
- Ultimate solution – social change, socio-economic rehabilitation of the marginalized

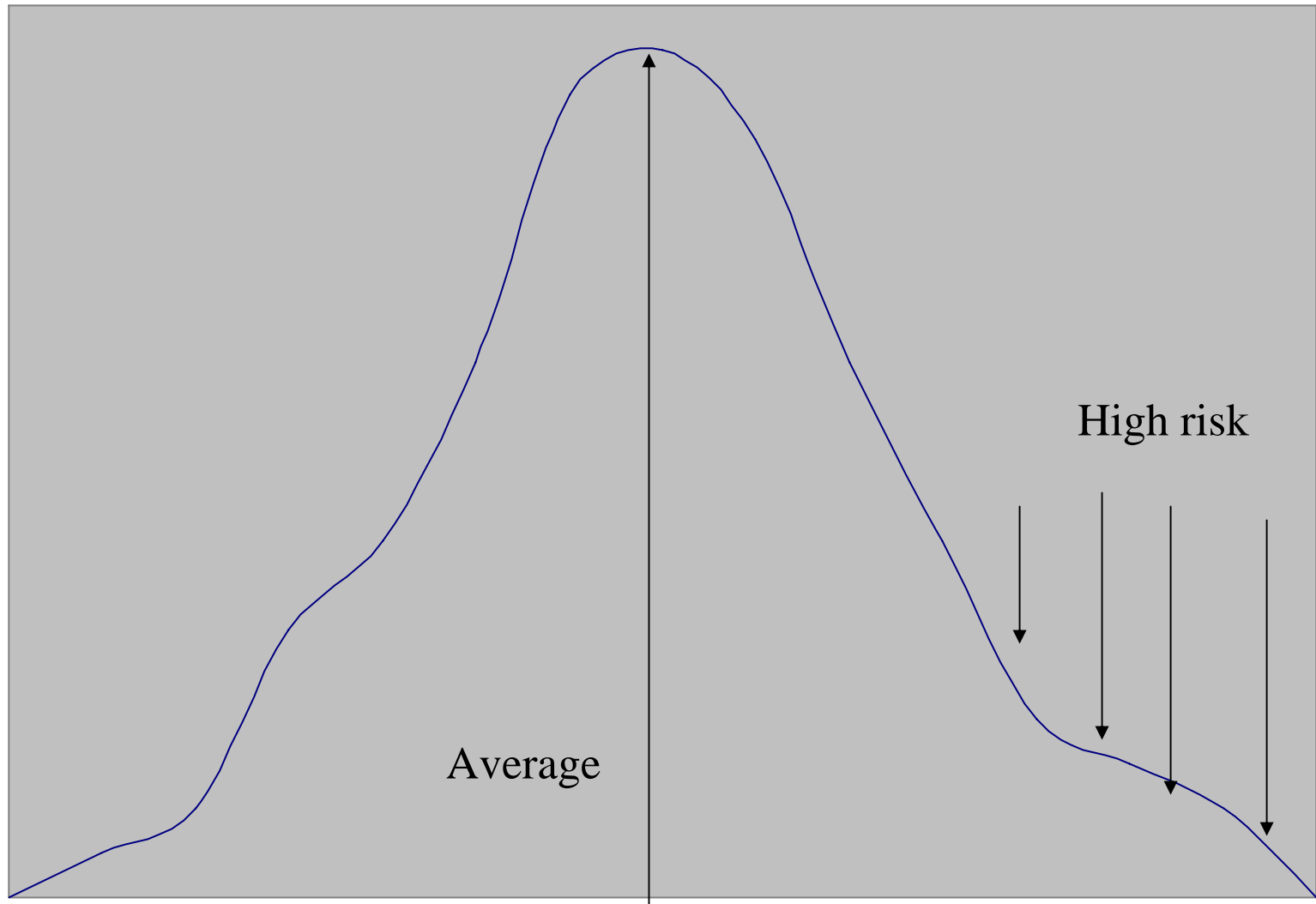
How much persuasive?

- If u can't find a woman, take a man
- Deputy is essential
- Rum till I die

Public Health Axiom

- Population average determines numbers of deviant individuals (e.g., alcohol, blood pressure, smoking, high risk behaviour)
- We are all responsible for all
- Let's think out of box

Population average has to change to reduce the high risk/ deviant individuals



Small steps, big rewards

- Post-test Form of HIV+ at MRC
- Encoding Vs name-based, confidential reporting
- Ethnic data
- TPHL data analysis
- Explore possible synergies to avoid
 - Duplication & wastage of resources

Big steps, big rewards

- AIDS notifiable disease
- Private sector involvement
- Behavioural studies, surveys
- TB & STD: co-morbidity

Surveillance Operational Guidelines

- Roles & responsibilities
 - National, Region, County
- Reporting
 - Who, whom, when, what
 - Flow chart & formats
- Data management
 - Security, confidentiality, coding

Salient features

- Provider requests test
 - Public & private sector including laboratories
- TPHL reports positive test results to
 - Provider, CMOH and NSU
- County gets the post-test form filled-out and sends to NSU on weekly basis
- County reports monthly summary to RHA
- RHA plans & implements programmes
- NSU reports quarterly & annually

Salient features

- NSU nurses fills-out post-test form of the AIDS cases found in the 4 major hospitals during active surveillance
- RHA to assume above responsibilities once its surveillance unit is functional
- Important: confidentiality & security at all levels

Module 2: Integration of HIV Rapid Testing in HIV Programs



Learning Objectives

- Recognize need for HIV counseling and testing in HIV prevention programs
- Recognize need for “same-visit” HIV testing in prevention programs
- Know the value of “same-visit” HIV testing for some sites (VCT, PMTCT etc.)
- Know where “same-visit” HIV testing will be used in T&T



Content Overview

- Need for expanded access to HIV testing
- Need for more people to “know their status”
- Need to integrate testing into counseling and referral programs
- Need to integrate testing into prevention, care and support services



HIV/AIDS Program Strategy

“Innovative solutions must be found to dramatically increase the number of individuals who are tested and know their status.”

- Implementation and evaluation of new and effective programmes
- Scale-up of current testing, counseling and referral services

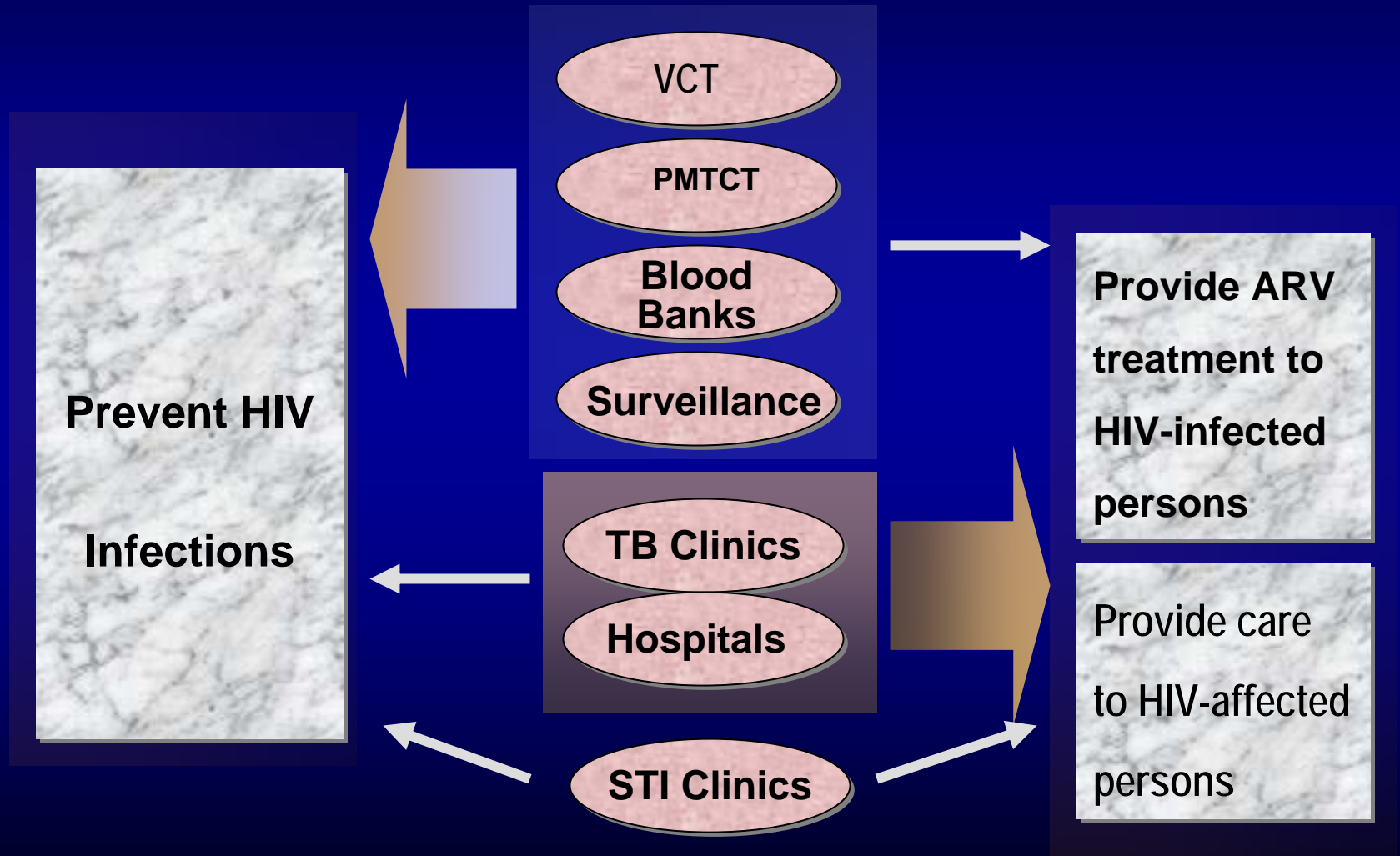


Current Status of HIV Testing

- 95% of those infected with HIV do not “know their status”
- Only 5-10% of all people have ever had an HIV test
- Less than 10% of pregnant women have had an HIV test
- Less than 10% of health care facilities offered testing and counseling in 2002



HIV Testing Occurs in a Variety of Settings



Lab workers

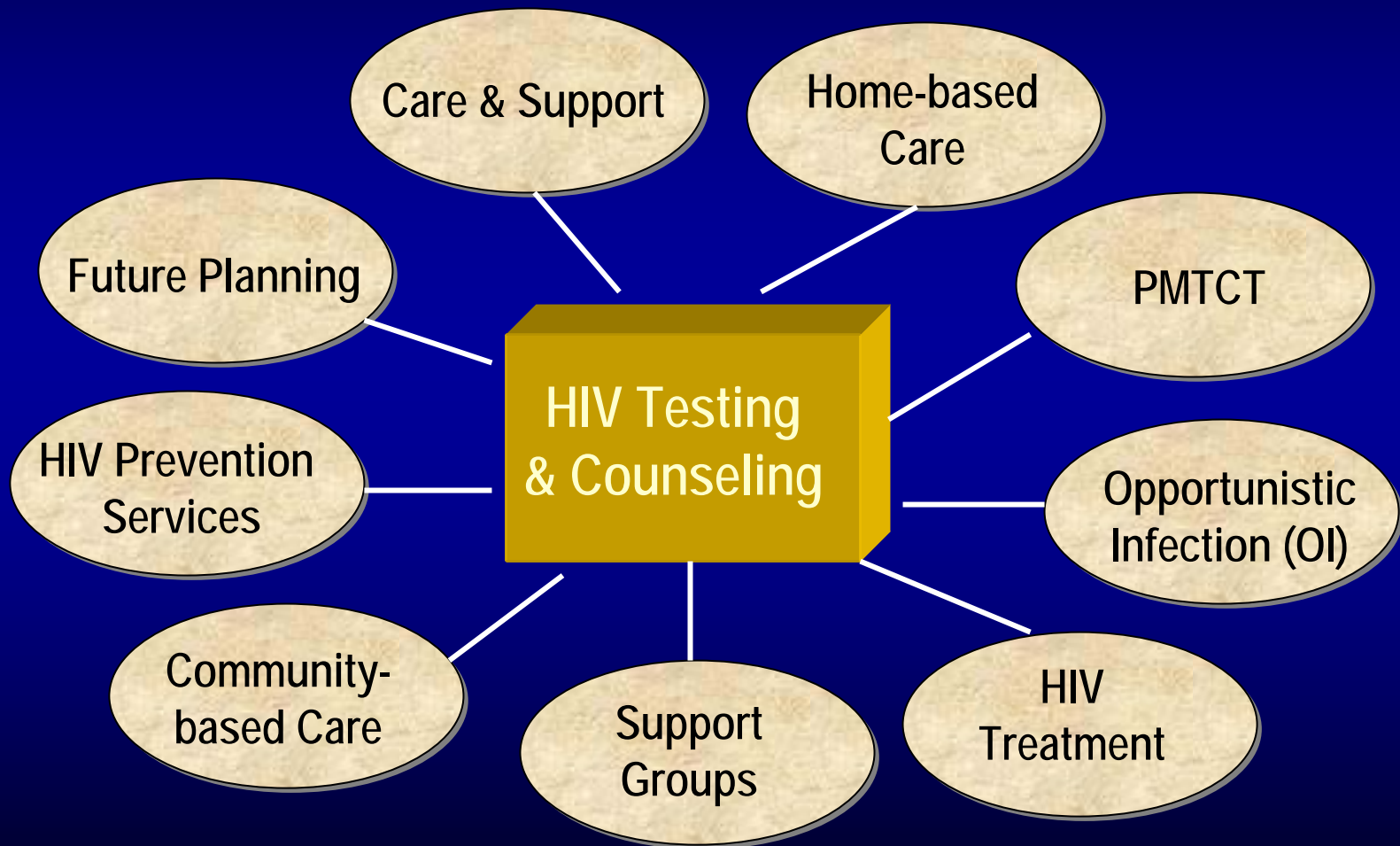


Health workers



Counselors

HIV Testing as an “Entry Point” to other HIV Services



Lab workers



Health workers



Counselors

Community-Based Counseling and Testing

- Members of the community are trained to provide counseling and testing
- Challenges: supervision; quality; confidentiality; linkage to care and treatment
- Support of community leaders is essential for success



Couples Counseling and Testing

- Facilitates disclosure and joint planning for risk reduction
- Increases utilization of HIV/AIDS services
- Allows for better family planning and care of children



Preventing Mother to Child Transmission (PMTCT)

- Prevention of HIV infection in pregnant women
- Prevention of unwanted pregnancies in HIV-infected women
- Prevention of HIV transmission from mothers to infants
- Provision of treatment and support to infected women and their families



Core Interventions for PMTCT

- “Same-visit” HIV testing and counseling
- Antiretroviral treatment
- Safer delivery practices
- Safer infant-feeding practices



Reasons for “Same-Visit” HIV Testing

- Clients can be tested on site
- More clients receive test results
- Immediate intervention (ART) is possible
- Reduce HIV transmission to infants
- Eliminate need to wait for lab test results
- Reduce chance of specimen “mix-up”



International Recommendations for Counseling and Testing in PMTCT

- Group pre-test information at ANC
- Individual pre-test counseling at ANC
- Routine HIV testing at ANC and at L&D
- “Same-day” testing at ANC and at L&D
- Individual post-test counseling
- Encouraging partner testing

Source: WHO's draft CT for PMTCT (2003), CDC's MMWR 2002; CDC's Dear Colleague letter (2003); Institute of Medicine. Reducing the odds. Preventing perinatal transmission of HIV in the United States. Washington, DC: National Academy Press, 1999



Summary

- Where can HIV counseling and testing be offered?
- What are the advantages of using “same-visit” HIV testing?
- What are special advantages of using HIV rapid testing in PMTCT?
- How does HIV testing help to support access to treatment ?



Module 3:

Overview of HIV Testing Technologies



Learning Objectives

At the end of this module, you will be able to:

- Discuss integration of HIV testing into other HIV/AIDS programmes and services
- Discuss the various testing technologies for HIV
- Explain the advantages and disadvantages of HIV rapid tests
- Recognize individual HIV test results as positive, negative or invalid

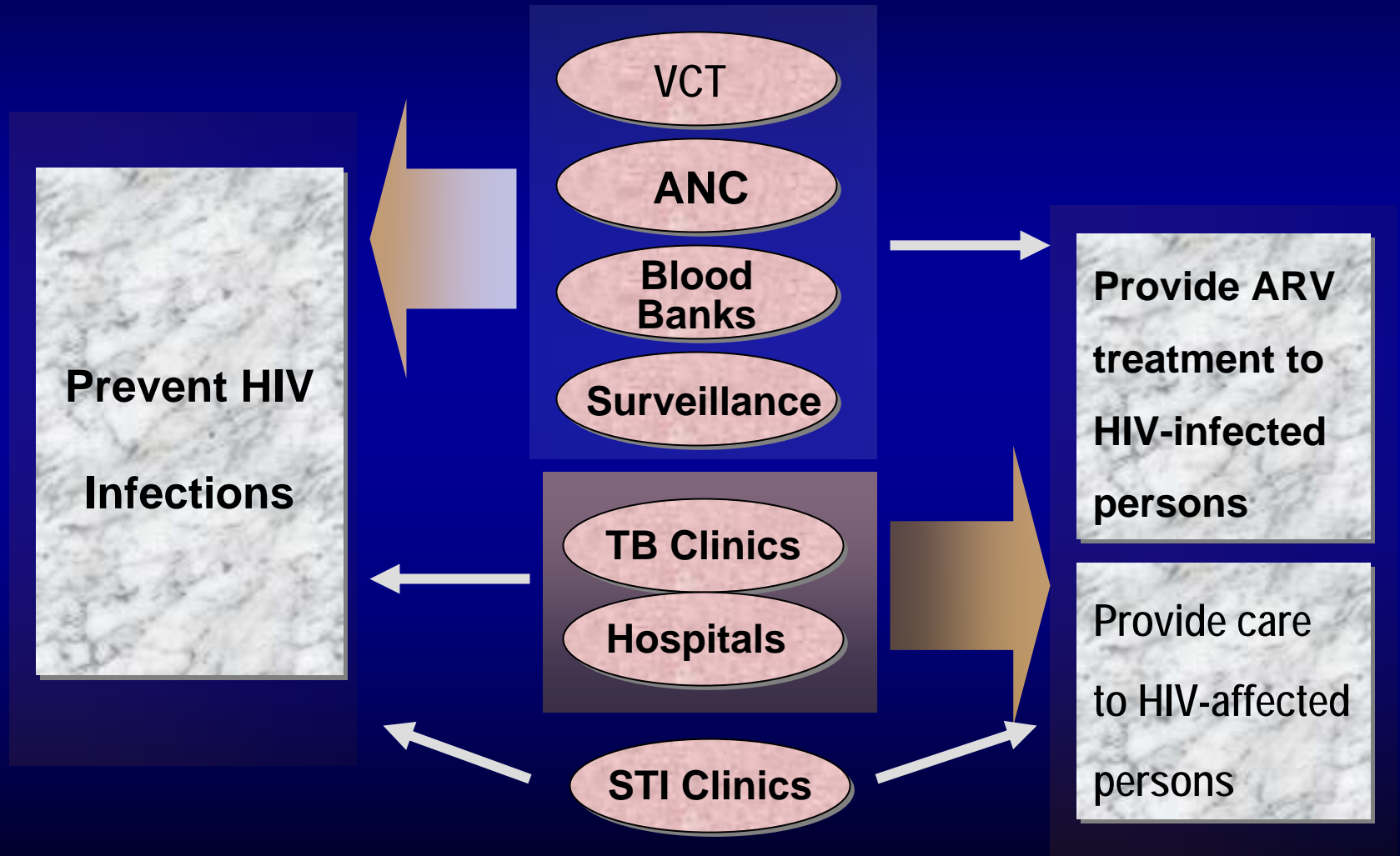


Content Overview

- Expansion of HIV rapid testing
- Types of HIV tests
- Challenges in HIV testing
- Advantages and disadvantages of HIV rapid testing
- Types of HIV rapid tests
- Reading individual test results



HIV Testing Occurs in a Variety of Settings



Lab workers



Health workers



Counselors

Expansion of Testing Services

- Integrate HIV testing services into national health systems
- Introduce testing into non-traditional settings



Use of HIV Testing in the Continuum of Care

Use HIV testing to diagnose HIV infection



Initiate treatment with ARVs

Monitor effectiveness of ARVs
with diagnostics (viral load,
CD4)



Lab workers



Health workers



Counselors

Types of HIV Tests

- Serology (Antibody/Antigen testing)
 - Enzyme Immunoassays (EIAs)
 - Rapid tests
 - Western blot (WB)
- Lymphocytes
 - CD4 counts
 - CD8 counts
- Nucleic Acid
 - Viral Load
 - PCR



Challenges in HIV Testing

- Maternal antibody present in infants
- “Window” between infection and antibody appearance
- Not all HIV subtypes can be detected with a single test
- Other health conditions
- Laboratory requirements
- Technical skill

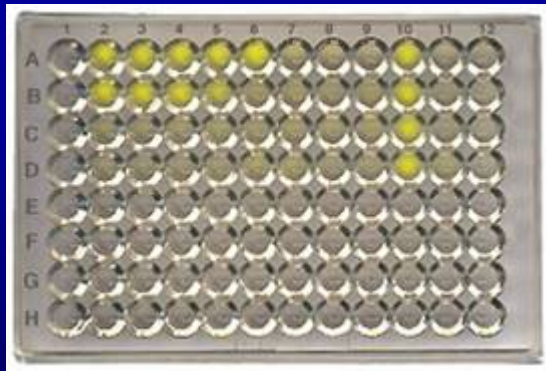


Enzyme Immunoassays (EIAs)

- Detect HIV antibodies to both HIV-1 and HIV-2
- Detect both HIV antibody and HIV antigen (close window period)
- Require sophisticated laboratory
- Require well trained lab personnel



Enzyme ImmunoAssays (EIAs)



Samples placed in individual wells for testing



Automated reader determines result of test



Lab workers



Health workers

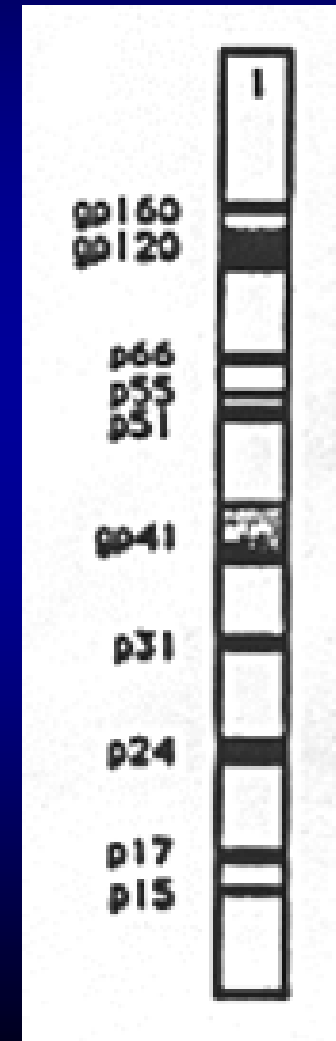
HIV Rapid Tests

- Detect HIV antibodies to HIV 1 and HIV 2
- Results comparable to EIA results
- Suitable for non-lab settings
- Non-lab personnel can be trained to test using these devices



Western Blot Assays

- Detects antibodies to specific HIV antigens
- Difficult to interpret
- Multiple standards for performance in use
- Expensive
- Limited availability



CD4 Cell Counts

- Follow clinical progress
- Monitor therapy
- Require trained staff
- Require sophisticated equipment



HIV Viral Load

- Molecular assay to measure HIV levels
- Used to monitor disease progression
- Used to monitor ARV response
- Requires sophisticated lab facility
- Requires highly trained personnel
- Expensive



HIV Test Complexity*

- Level 1: No laboratory facility or experience needed
- Level 2: Multi-step process is required; Centrifuge or other equipment required
- Level 3: Specific laboratory skills such as diluting are required
- Level 4: Sophisticated equipment and well-trained laboratory staff are required

*WHO Reports



HIV Rapid Testing permits expansion of services



Lab workers



Health workers



Counselors

HIV Rapid Tests: Advantages

- Increased access to testing
- Expanded numbers of testing sites
- “Same-visit” HIV test results
- Permits testing in non-lab settings
- No refrigerated storage required
- WHO Level 1 test complexity
- Non-lab staff can be trained to use the tests



HIV Rapid Tests: Disadvantages

- Monitoring quality of testing is difficult
- Testing may be seen as “deceptively easy”
- Designing training for non-lab testers is challenging
- Positioning rapid testing within national medical systems is challenging



Body Fluids Used for HIV Rapid Testing

- Serum
- Plasma
- Whole blood
- Oral fluids



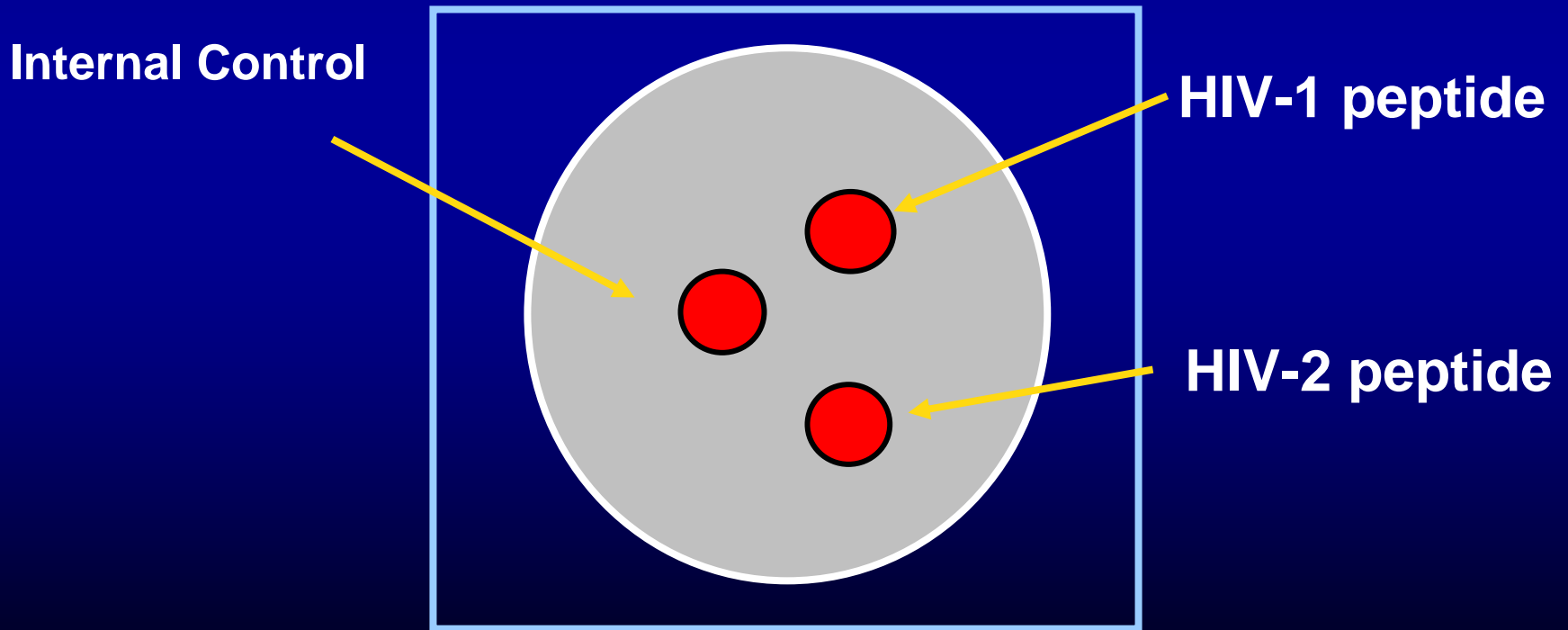
Three Formats of HIV Rapid Tests

- Immunoconcentration (flow-through device)
- Immunochromatography (lateral flow)
- Particle agglutination



Immunoconcentration Principle

HIV-antibody links to bound HIV-antigens
forming colored spots



Lab workers



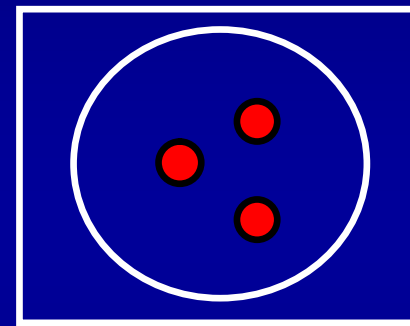
Health workers

Immunoconcentration Tests

These devices are also called “Flow-Through” Devices.

Two brand names are:

- Multi-Spot
- Genie II



Top view



Side view



Reading Results: Genie II



Negative



Positive



Lab workers

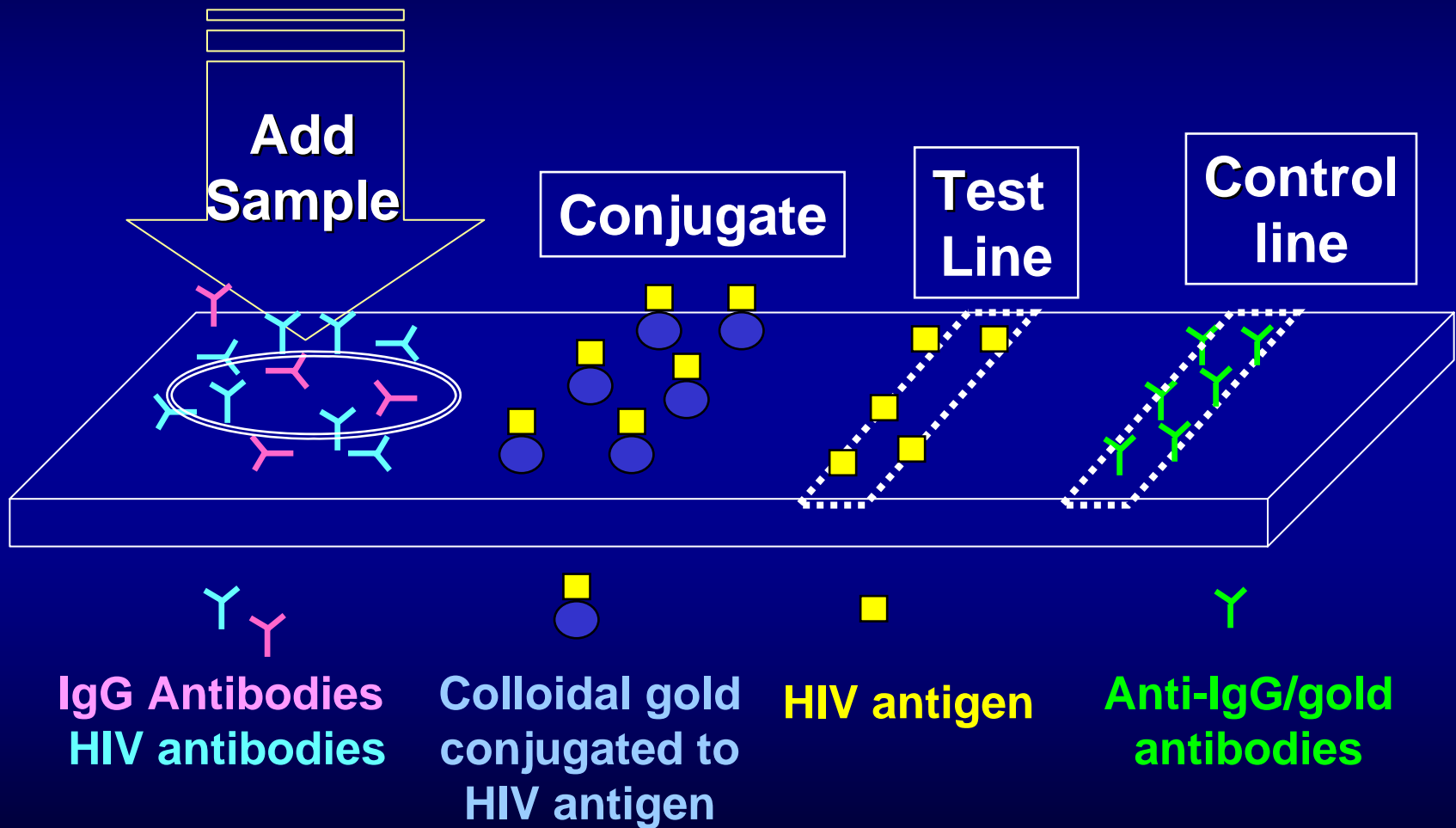


Health workers



Counselors

Immunochromatography Principle



Lab workers

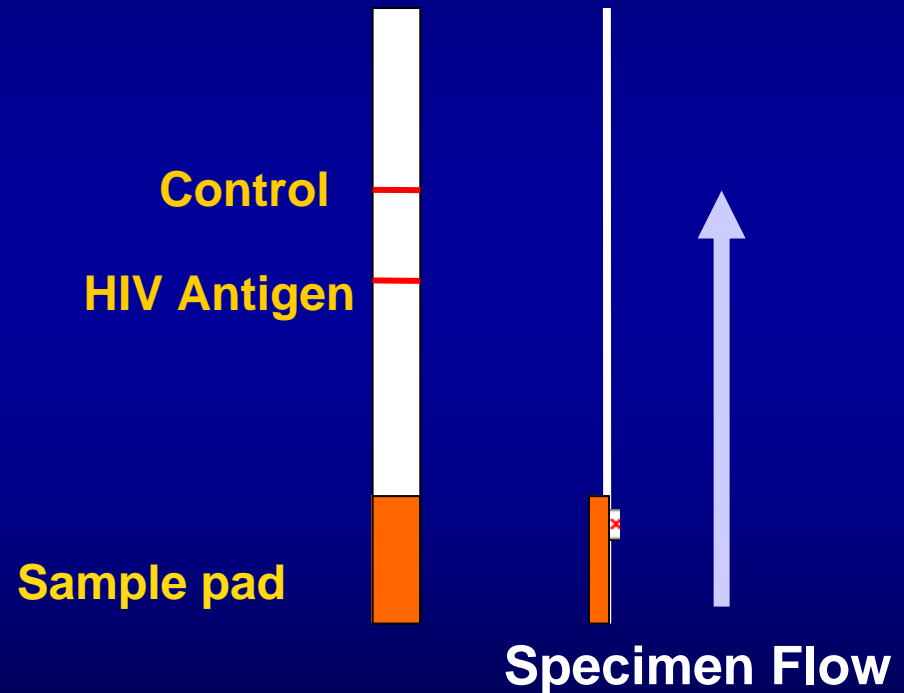


Health workers

Immunochromatography Tests

Lateral Flow Devices

- Determine
- Hema-Strip
- OraQuick
- Unigold
- Stat-Pak

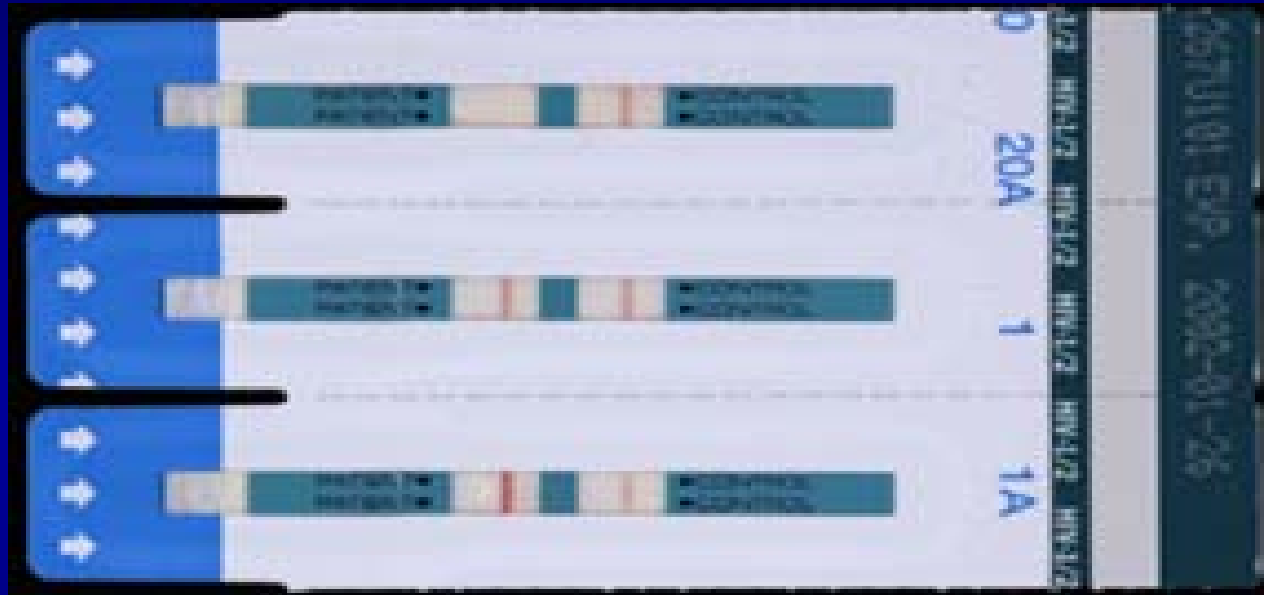


Reading Results: Determine

Negative

Positive

Positive



Sample Pad

Test line

Control line



Lab workers



Health workers



Counselors

Reading Results: OraQuick



Negative

Positive

Positive



Lab workers



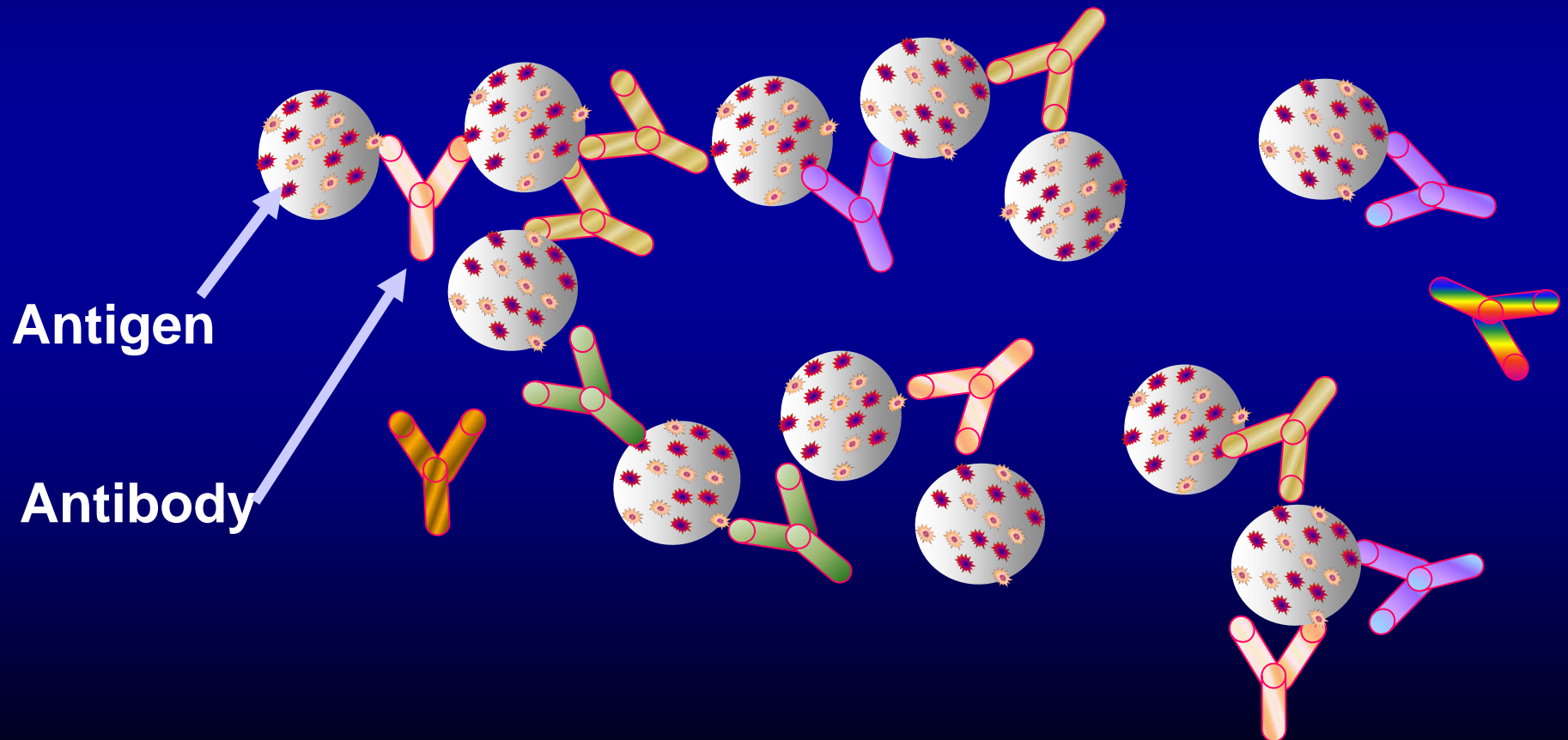
Health workers



Counselors

Particle Agglutination Principle

Anti-HIV antibodies bind to the antigen-coated latex particles.



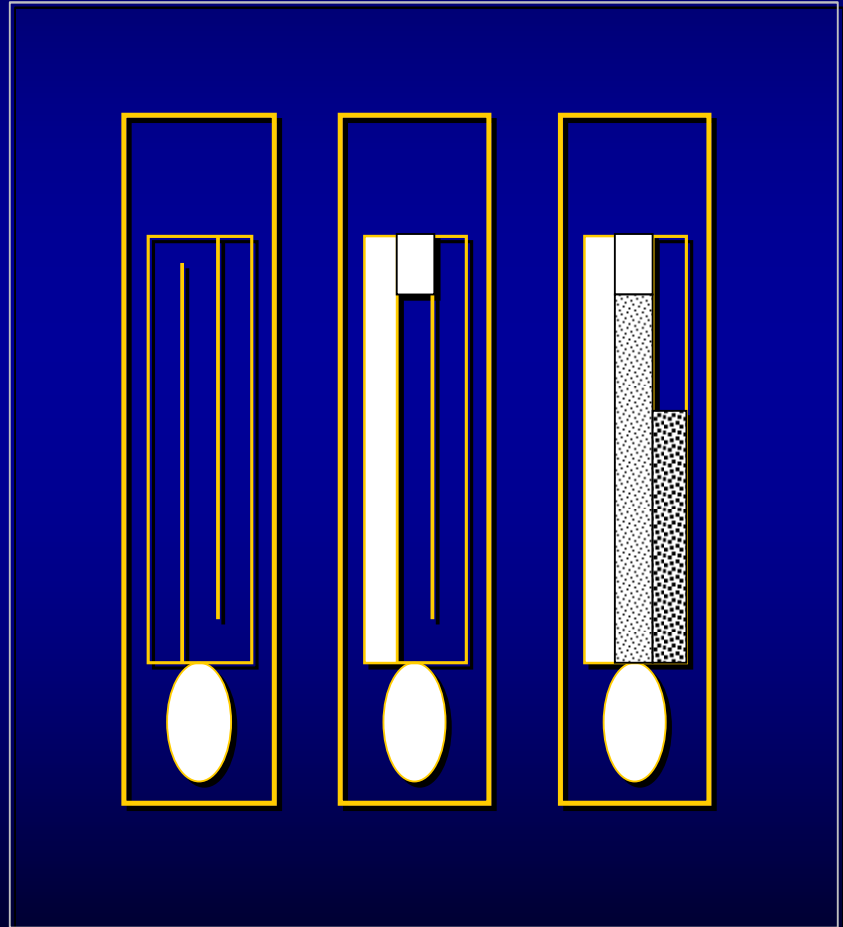
Lab workers



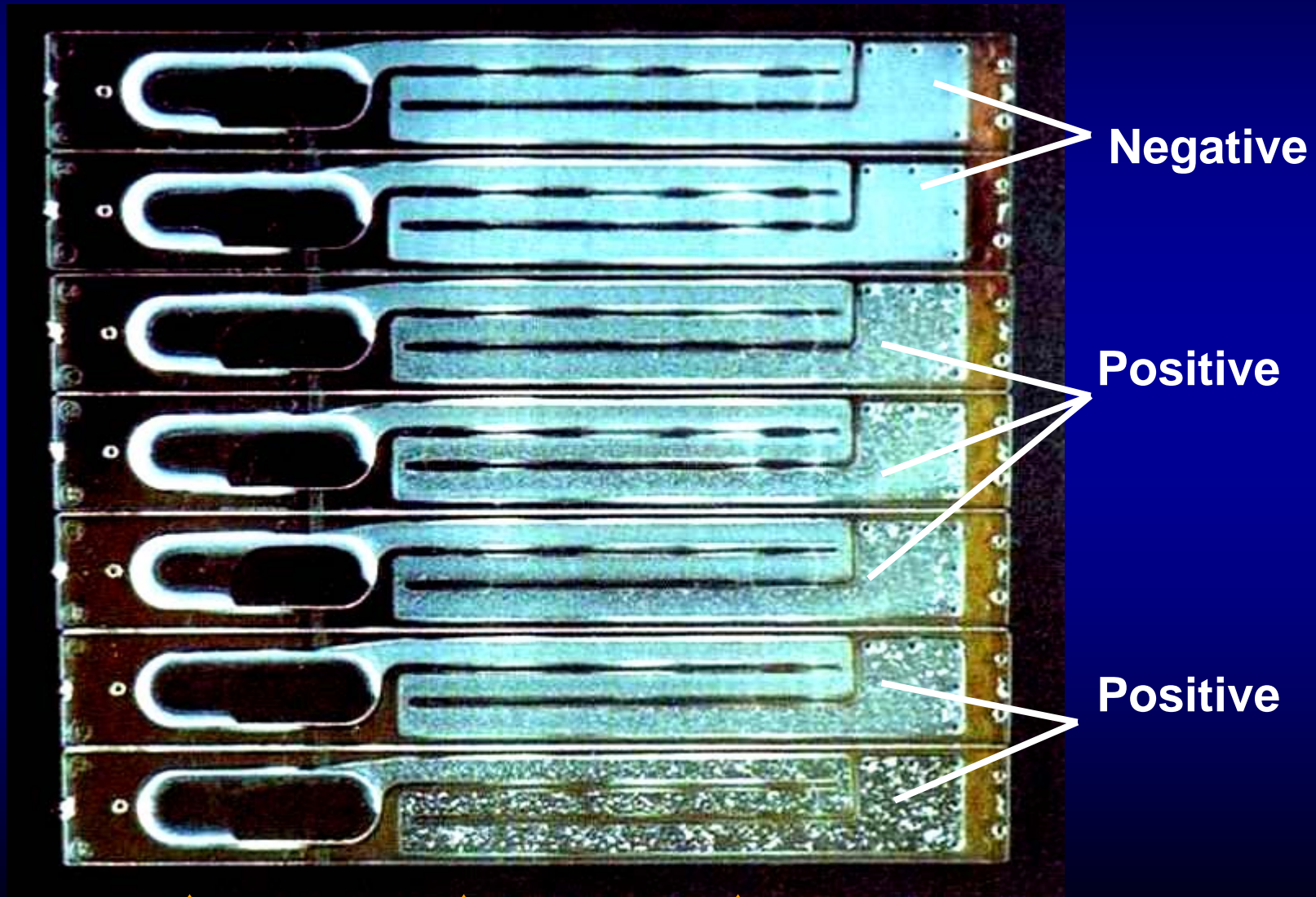
Health workers

Agglutination Tests

- Capillus
- Serodia



Reading Results: Capillus



Lab workers



Health workers



Counselors

Results for HIV Rapid Tests

Positive

- Test band
- Control band

Negative

- Control band only

Invalid

- No control band present
- Repeat with new device.



Exercise: Interpreting Individual HIV Rapid Test Results

- *Refer to Participant Manual*
- *Work alone to determine individual test results*
- *3 Minutes*



Key Messages

- HIV rapid tests are reliable
- HIV rapid tests require training, supervision, and monitoring
- No single test result can be used to diagnose HIV infection



Summary

- What are rapid tests?
- List three advantages of HIV rapid testing.
- What is WHO Level 1 test complexity?
- Why are HIV viral load tests needed?
- How many types of HIV rapid test results are possible?



Module 4:

HIV Testing Algorithms



Learning Objectives

At the end of this module, you will be able to:

- Define parallel and serial testing algorithms
- Define national testing algorithms
- Explain test selection for the MOH TT “same-visit” HIV rapid testing algorithm
- Describe the MOH TT testing algorithm
- Define HIV status using an algorithm



Content Overview

- Testing strategies
- Testing algorithms
- National algorithms
- MOH TT national testing algorithm
- Interpreting HIV test results



Strategies and Algorithms

- **Strategy** – Testing approach used:
 - Blood Safety
 - Surveillance
 - Diagnosis
- **Algorithm** – combination and sequence of tests used in a given strategy



HIV Test Performance

- No test is 100 % sensitive
- No test is 100 % specific
- No single HIV test result is sufficient to diagnose HIV infection
- A combination of results (an algorithm) is essential to diagnose HIV infection



Diagnostic Algorithms

- All diagnostic HIV testing is based on at least 2 test results*
- When the first two tests are concordant, the result can be reported
- When the first two tests are discordant, a third test must be performed
- The result of the third test is the algorithm result

*WHO recommendations



Ideal Algorithm Tests are:

- Highly sensitive
- Highly specific
- Based on different antigens
- Routinely available
- Easy to use
- Stored at room temperature



National Testing Algorithms

Advantages:

- Country-wide standardization
- Simplified procurement
- Simplified supply management
- Uniform training
- Quality monitoring



National Algorithm Development

- Select type of algorithm needed*
- Review available information
- Select tests for inclusion
- Develop protocol
- Pilot test selected algorithm
- Expand to national scale
- Review testing algorithms annually

*WHO recommendations



MOH TT Algorithm Selection*

- Algorithm should provide “same-visit” HIV test results
- Algorithm should be suitable for use in “non-lab” locations
- “Same-visit” test results can be obtained using “diagnostic” algorithms*
- Diagnostic algorithms require three tests
- Non-lab locations require use of HIV rapid tests

*WHO recommendations

MOH TT Algorithm Test Selection

- WHO evaluation
- CAREC evaluation
- Guyana evaluation
- Brazil evaluation
- Temperature for shipment/storage
- Ease of use
- Type of specimen (whole blood)
- Cost
- Procurement reliability



The Algorithm Is Important



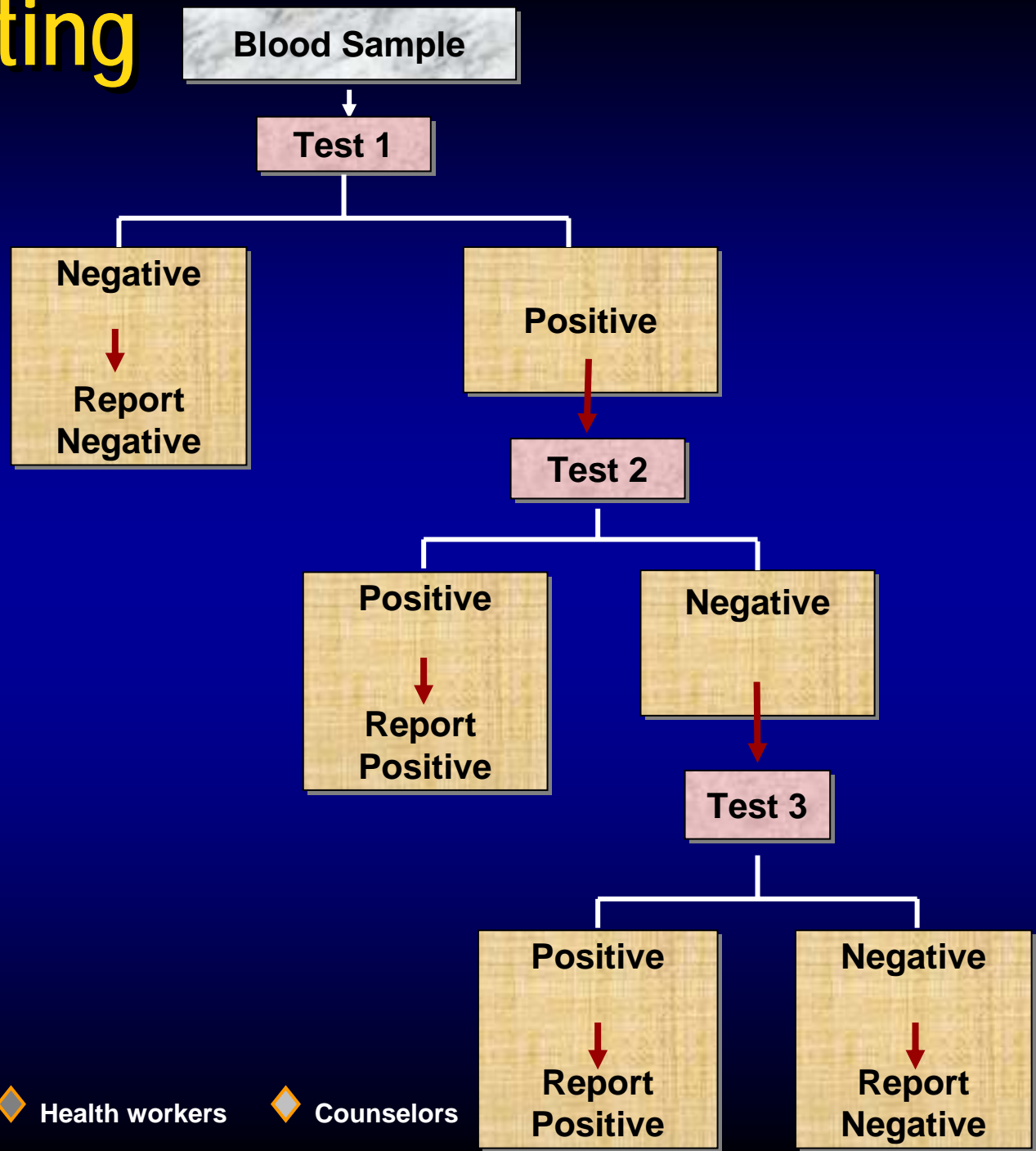
**Always follow the
algorithm!**

HIV Diagnostic Algorithms*

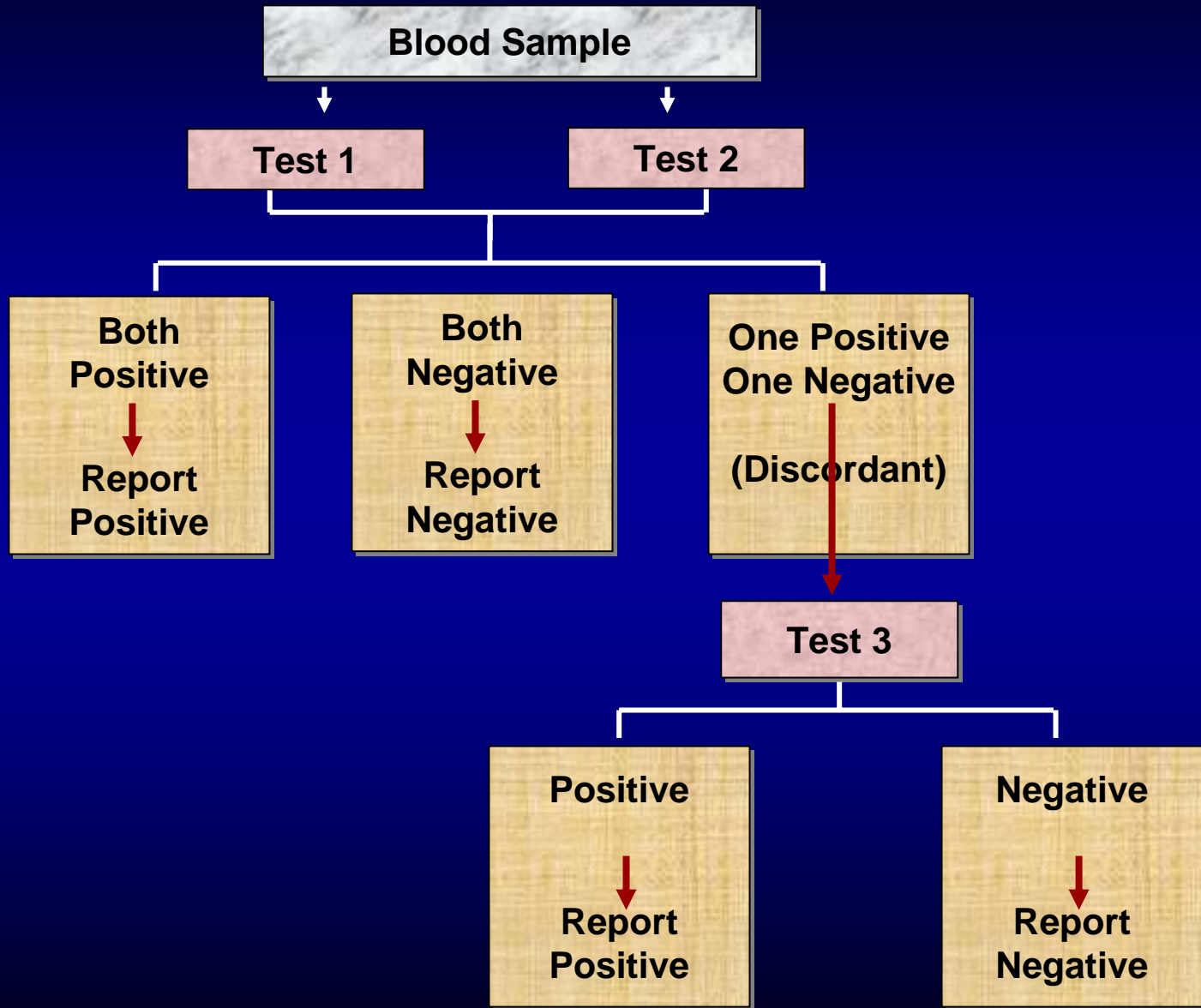
- Serial algorithms are suitable where prevalence of HIV exceeds 10%
- Parallel algorithms are needed where prevalence of HIV is less than 10%
- In TT, HIV prevalence is less than 10% and diagnosis requires a parallel algorithm

*WHO definitions

Serial Testing Algorithm



Parallel Testing Algorithm



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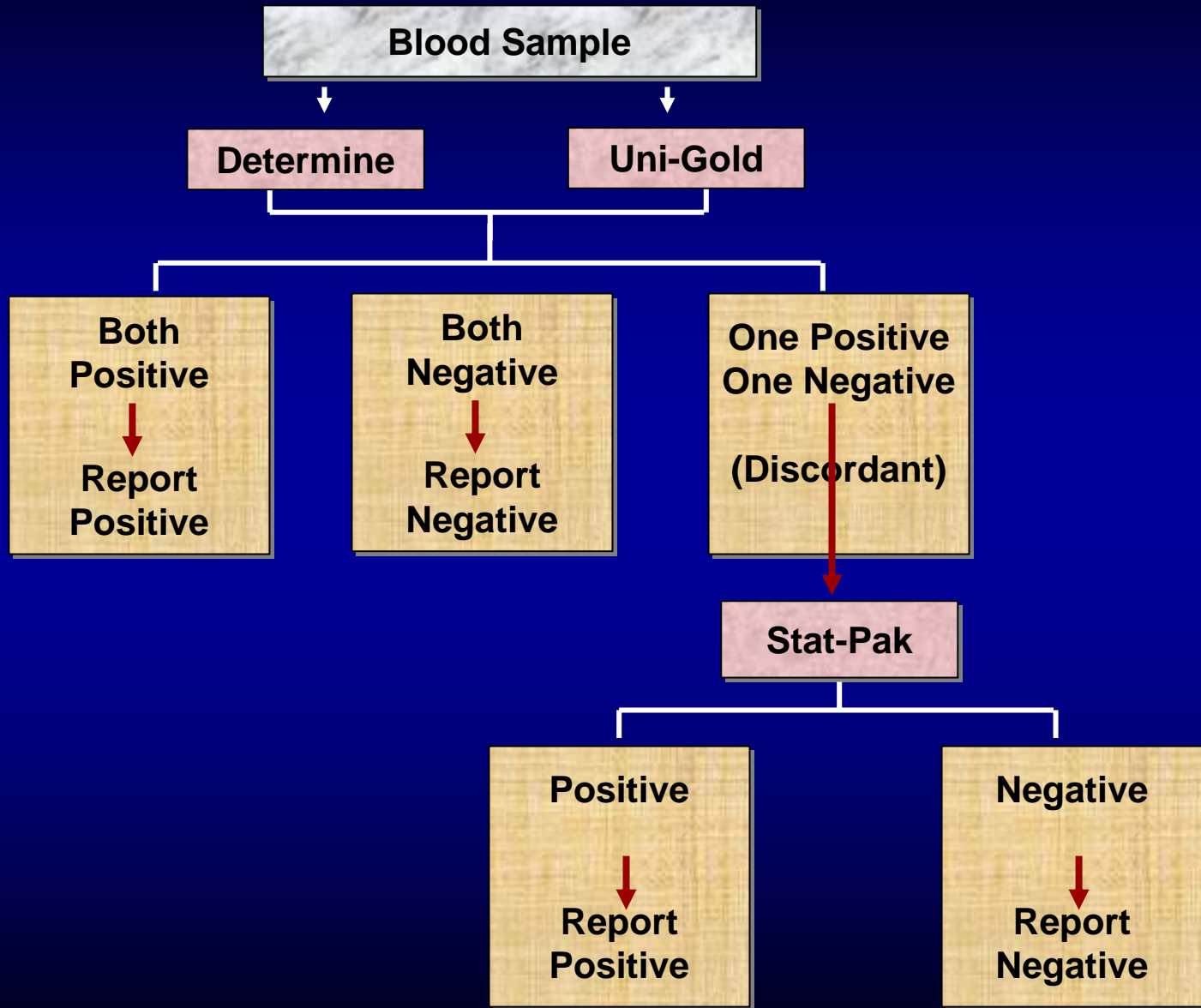


Health workers



Counselors

MOH TT Algorithm



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HIV Testing Results: Parallel Algorithm

| TEST 1 | TEST 2 | TEST 3 | HIV Status |
|----------|----------|--------|------------|
| Negative | Negative | | |



HIV Testing Results: Parallel Algorithm

| TEST 1 | TEST 2 | TEST 3 | HIV Status |
|----------|----------|--------|------------|
| Negative | Negative | | Negative |



HIV Testing Results: Parallel Algorithm

| TEST 1 | TEST 2 | TEST 3 | HIV Status |
|----------|----------|--------|------------|
| Positive | Positive | | |



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HIV Testing Results: Parallel Algorithm

| TEST 1 | TEST 2 | TEST 3 | HIV Status |
|----------|----------|--------|------------|
| Positive | Positive | | Positive |



Lab workers



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HIV Testing Results: Parallel Algorithm

| TEST 1 | TEST 2 | TEST 3 | HIV Status |
|----------|----------|----------|------------|
| Negative | Positive | Negative | |



Lab workers



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HIV Testing Results: Parallel Algorithm

| TEST 1 | TEST 2 | TEST 3 | HIV Status |
|----------|----------|----------|------------|
| Negative | Positive | Negative | Negative |



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HIV Testing Results: Parallel Algorithm

| TEST 1 | TEST 2 | TEST 3 | HIV Status |
|----------|----------|----------|------------|
| Positive | Negative | Positive | |



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HIV Testing Results: Parallel Algorithm

| TEST 1 | TEST 2 | TEST 3 | HIV Status |
|----------|----------|----------|------------|
| Positive | Negative | Positive | Positive |



HIV Testing Results: Parallel Algorithm

| TEST 1 | TEST 2 | TEST 3 | HIV Status |
|----------|----------|----------|------------|
| Negative | Positive | Positive | |



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HIV Testing Results: Parallel Algorithm

| TEST 1 | TEST 2 | TEST 3 | HIV Status |
|----------|----------|----------|------------|
| Negative | Positive | Positive | Positive |



Lab workers



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Questions?

- When can HIV be diagnosed with a single test?
- What is an algorithm?
- Why is the MOH TT algorithm parallel?
- What does it mean when test results are concordant? Discordant?
- What tests are in the MOH TT algorithm?



Module 5: Quality of HIV Rapid Testing

A Systems Approach to Quality



Learning Objectives

At the end of this module, you will be able to:

- Explain the systems approach to quality
- Identify the elements of quality in HIV rapid testing
- Recognize factors that compromise quality
- Describe your role in assuring quality in HIV testing



Content Overview

- How to achieve quality
- How to maintain quality
- Essential elements of a quality system
- Quality assurance in HIV rapid testing
- Your role in quality of HIV rapid testing



What Is “Quality”?



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What Is “Quality”?

- Reliable
- Reproducible
- Accurate
- Provides satisfaction
- Meets expectations

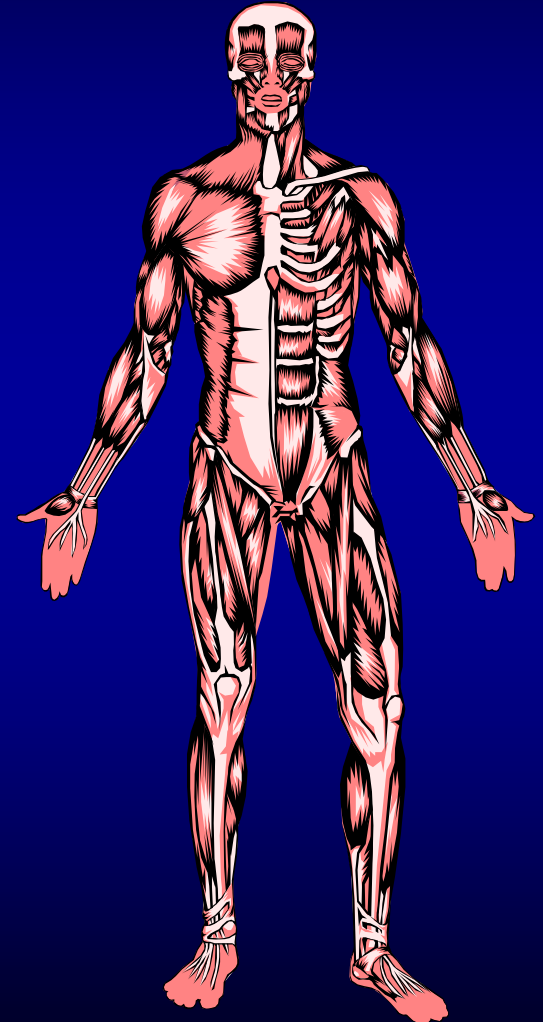


A Systems Approach to Quality

- Considers all components within a system
- Identifies the connections and relationships among the components

Example: the human body system

A pain in one component may be caused by a disorder in another component

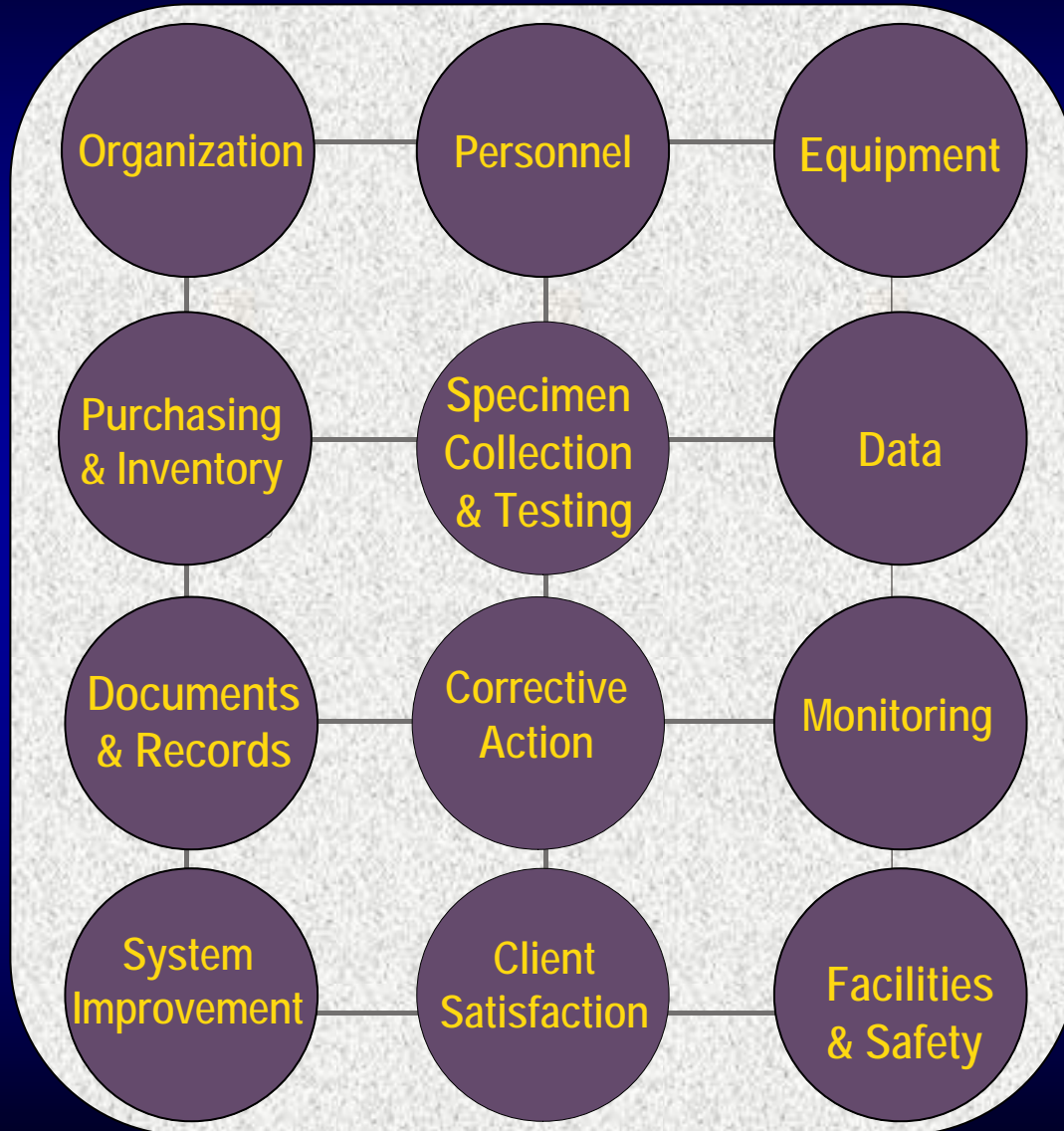


Benefits of Quality Systems

- Monitors all components of testing
- Detects and corrects errors
- Improves reproducibility between testing sites
- Helps contain costs



T&T Quality Health Care System



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Organization



Personnel

Planning

Hiring

Retention

Training

Supervision

Performance



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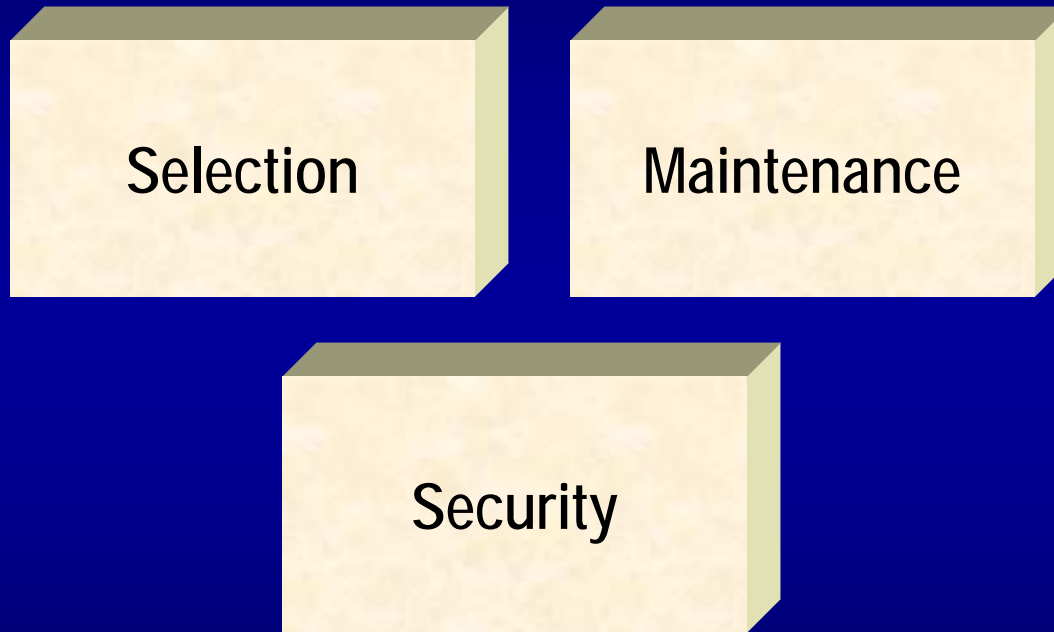


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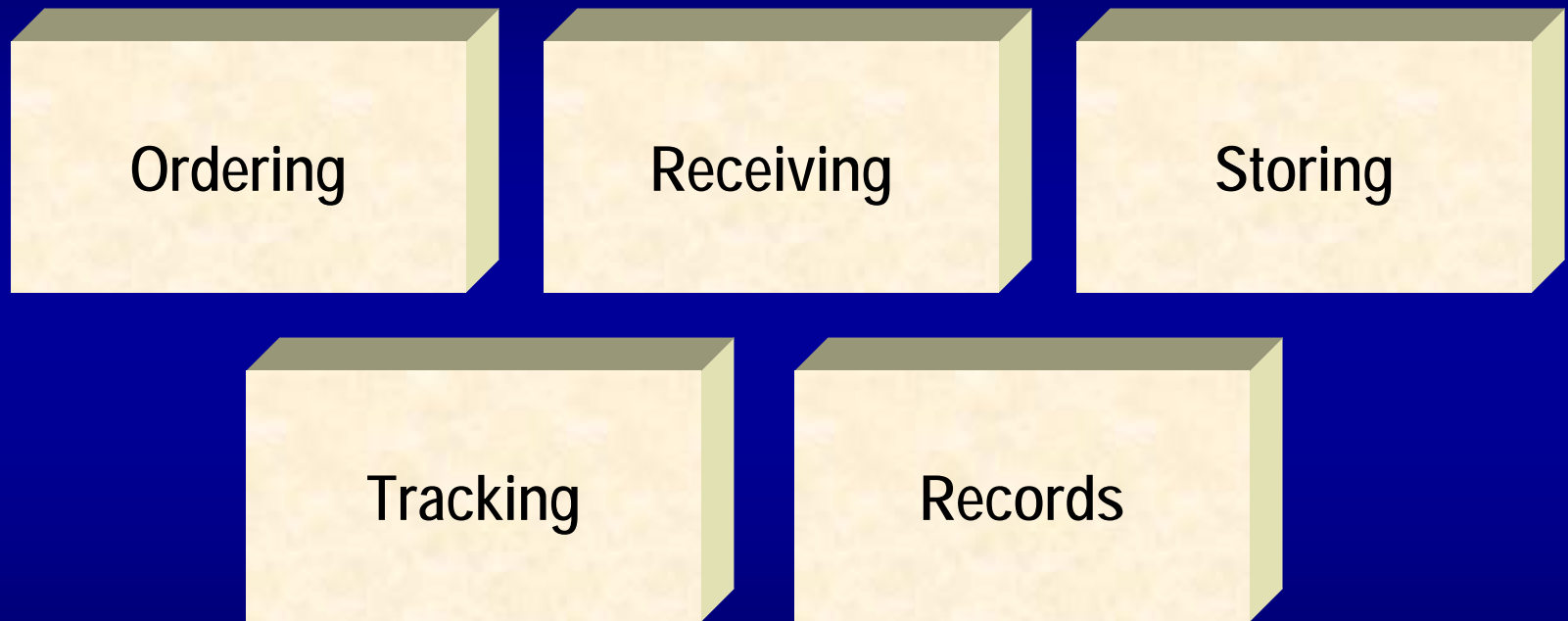


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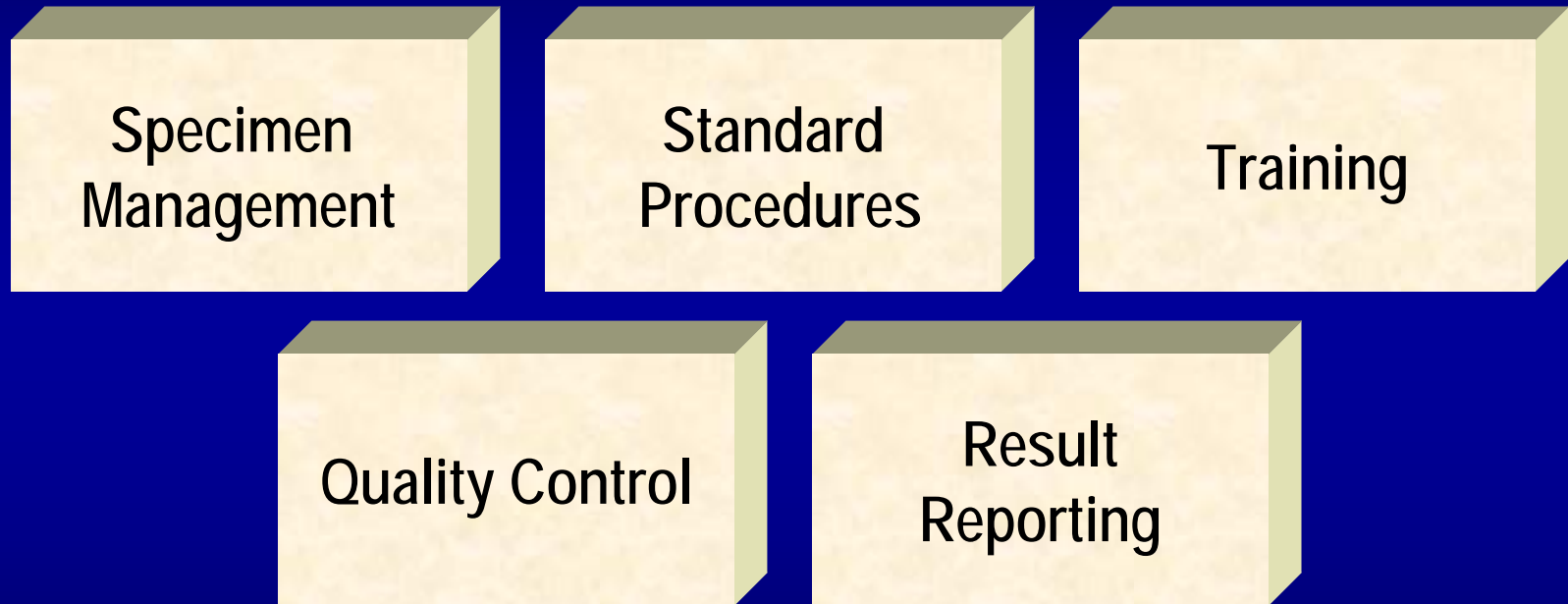
Equipment



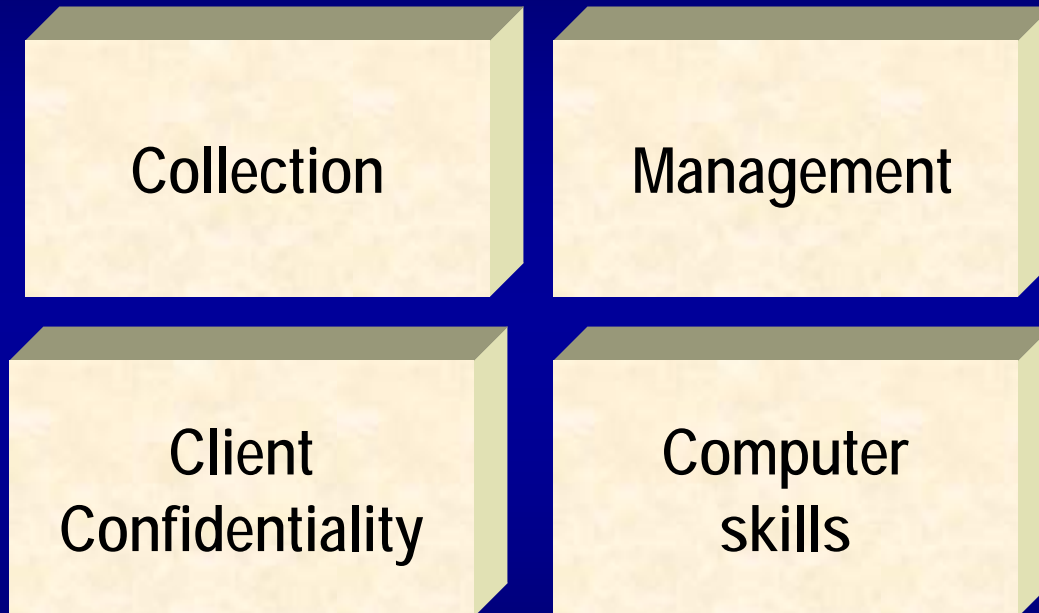
Purchasing and Inventory



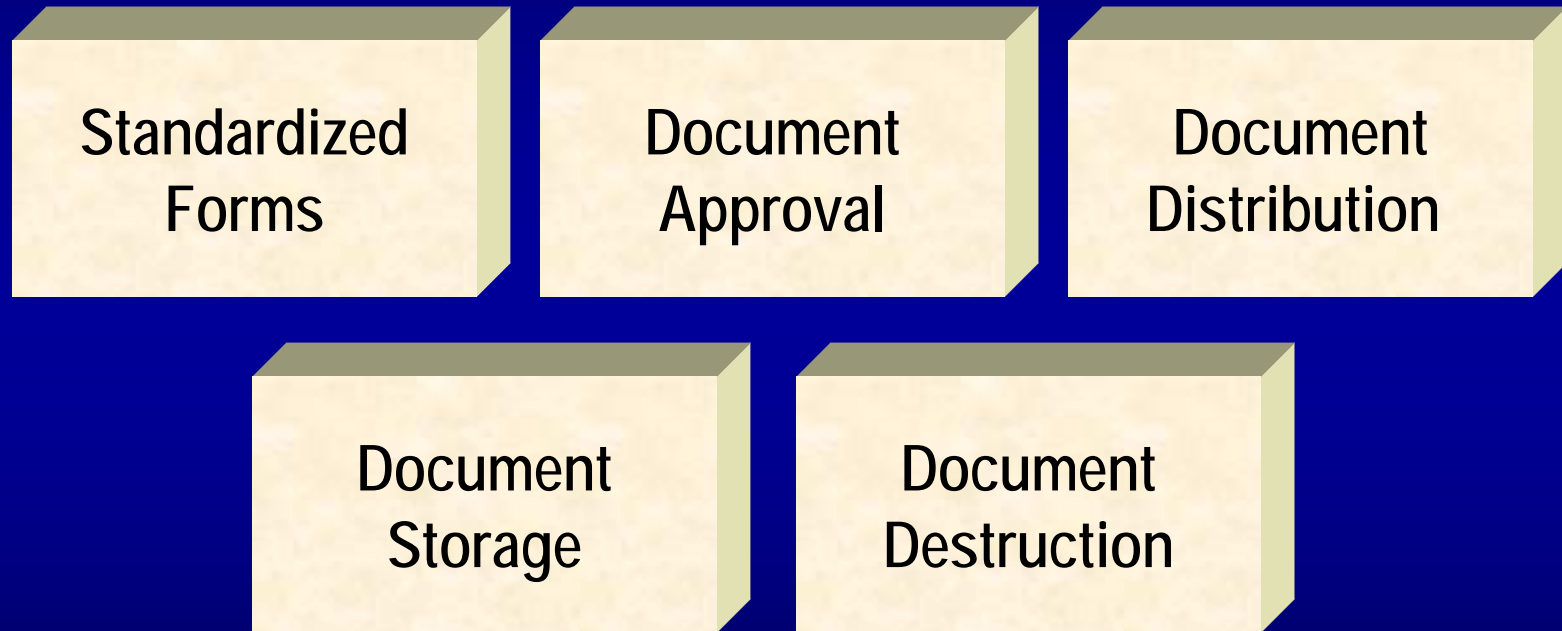
Spec Collection & Testing



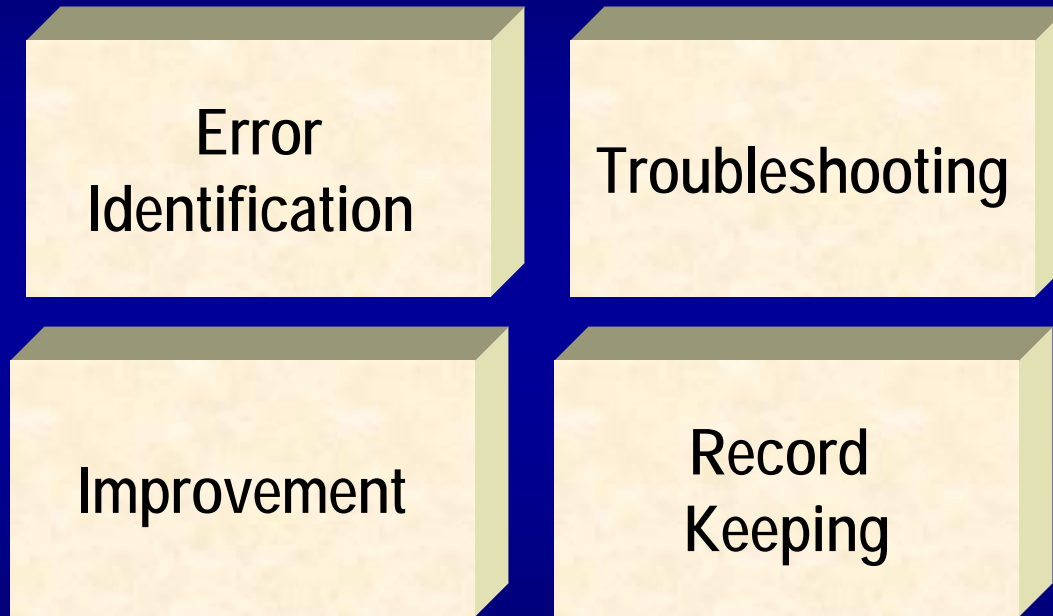
Data



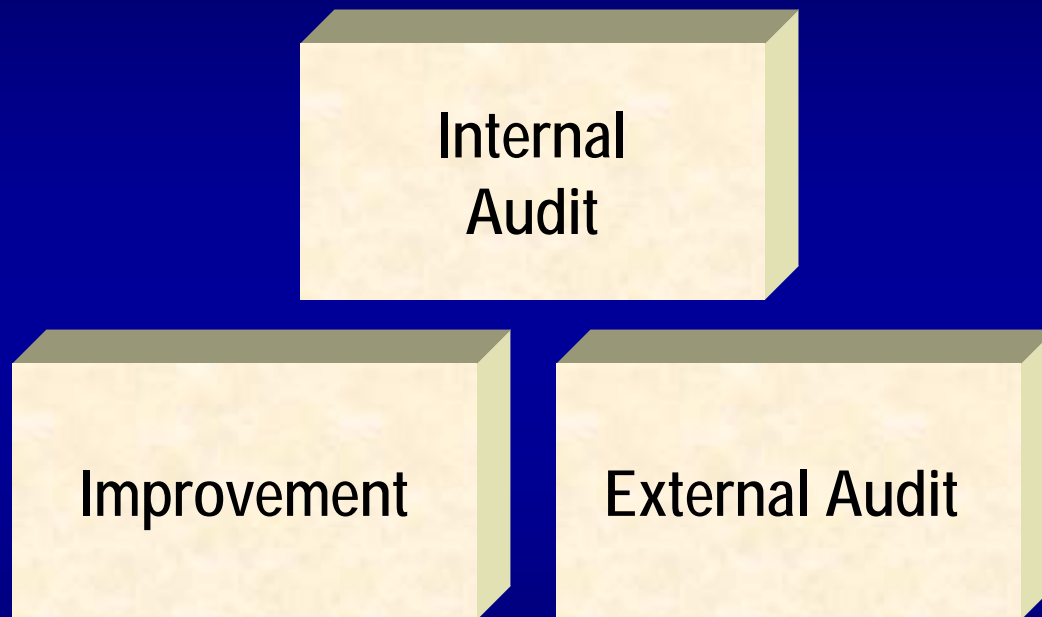
Documents and Records



Corrective Action



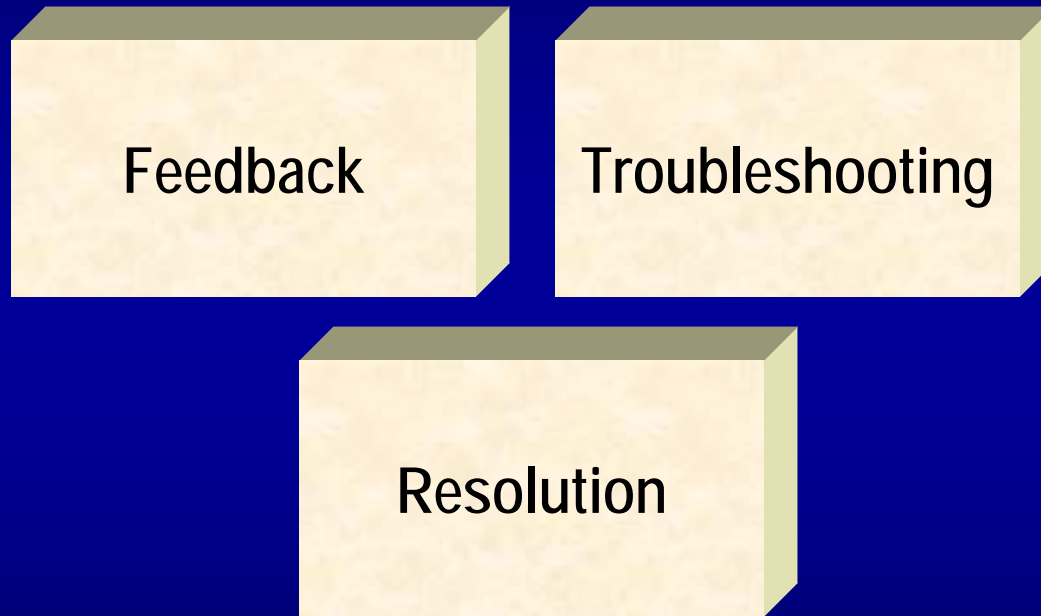
Monitoring



System Improvement



Client Satisfaction



Facilities & Safety

Universal
Precautions

Safety Policy

Confidentiality

Standard
Procedures

Records



Lab workers



Health workers



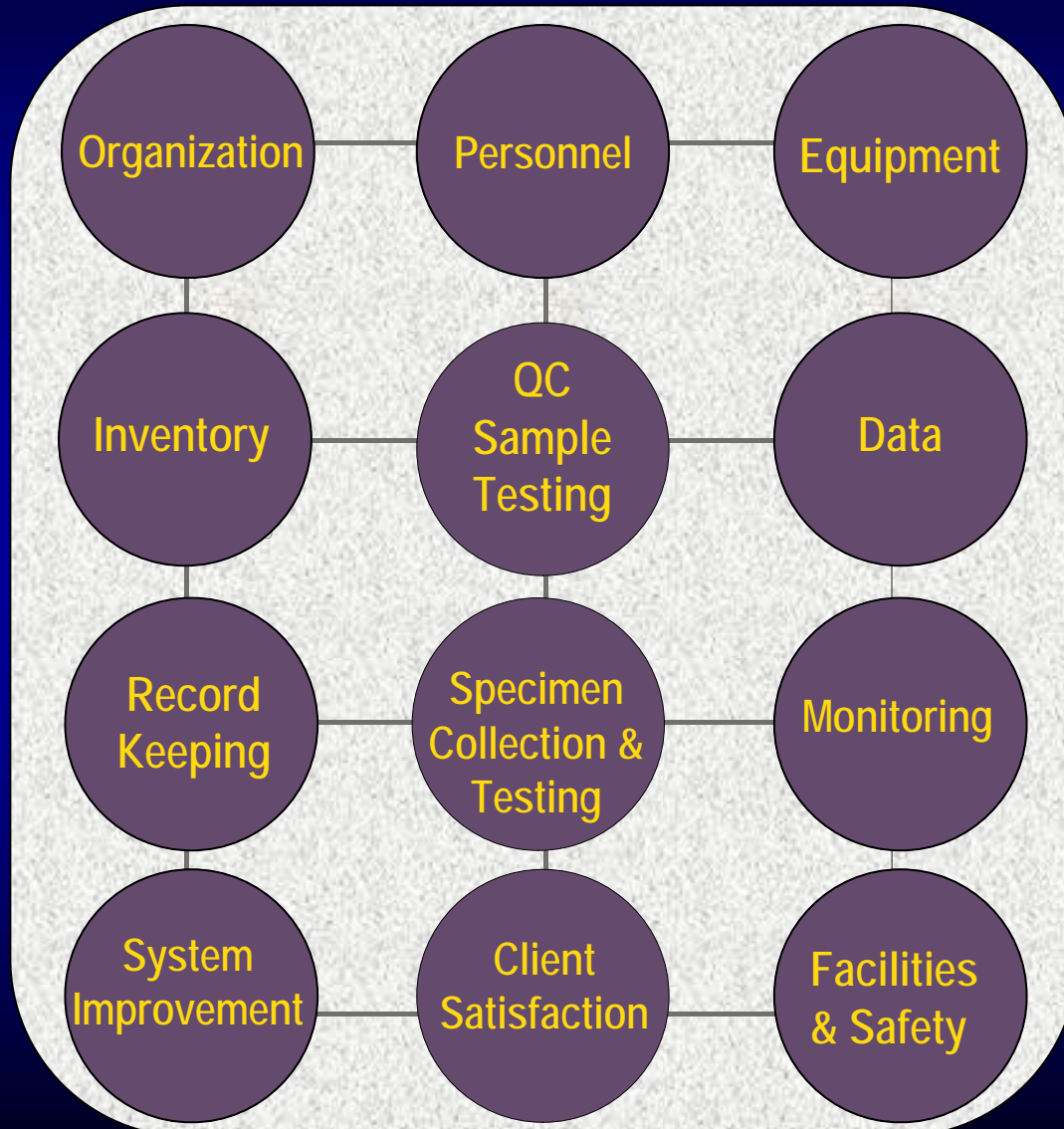
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Quality Testing Systems

Quality system components include all activities, supplies, and personnel that contribute to test results.



Quality HIV Testing System



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Activity: Are You “Positive” or “Negative?”

Participants take turns tossing the cabbage ball. When you catch the ball,

- Peel a statement off the ball
- Read out loud your statement to the group
- Based on the statement, go to:
 - ✂ The Positive Circle or
 - ✂ The Negative Circle



Who Is Responsible for Quality?



EVERYONE!

- Laboratory and program staff establish quality procedures.
- Test site personnel implement quality procedures.



Why Do Errors Occur?

- Responsibilities unclear
- Written procedures lacking
- Written procedures not followed
- Training incomplete
- Records improperly monitored
- Supplies stored improperly
- QC samples not tested



Preventing and Detecting Errors

- Record temperatures
- Review inventory
- Test QC samples
- Maintain QC Sample Log
- Use designated testing space
- Follow SOPs
- Complete records for each client



Testing Errors

- Algorithm not followed
- Individual test SOPs not followed
- Incorrect time for reading test
- Wrong buffer used for testing
- Expired reagents used for testing
- Finger-stick fails to give enough blood
- Incorrect information recorded
- Improper waste disposal



Quality in HIV Rapid Testing

- Makes test results uniform among testing sites
- Sets a standard for HIV testing
- Meets/exceeds customer expectations
- Provides approach to correcting problems
- Provides data for improvement of testing
- Reduces costs

No test is foolproof!



Summary

- Why do errors occur?
- What errors could occur in HIV rapid testing?
- Where is quality in a testing site?
- How can you reduce errors in testing?
- How will errors impact clients?

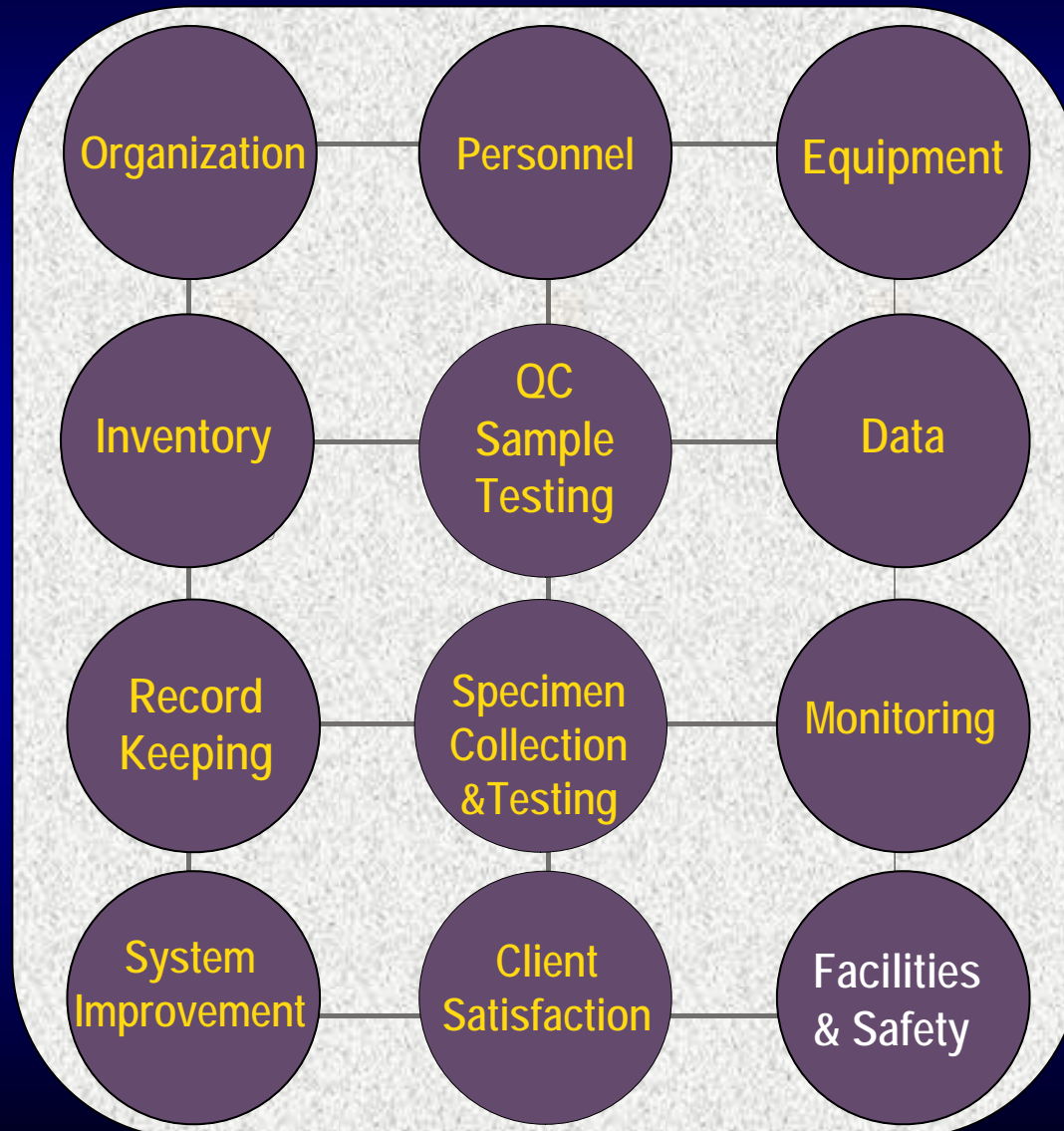


Module 6: Safety at the HIV Rapid Testing Site

Learning to “Think like a lab person” (Part 1)



Quality HIV Testing System



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Learning Objectives

At the end of this module, you will be able to:

- Follow personal health and safety practices
- Maintain a clean and organized workspace
- Dispose of infectious materials
- Describe what to do in the case of an accident
- Follow safety procedures and keep safety records



Content Overview

- Safety practices include how to:
 - Develop safety habits
 - Properly dispose of waste
 - Keep safety records



What is Safety?

Safety is taking precautions to protect you, the client and others against infection, accident or injury.



Why Is Safety Important?

We cannot wait until a serious accident or illness occurs before we implement safe practices



Who Needs to be safe?

- The client
- The tester
- Others



Universal Safety Precautions

Every specimen should
be treated as though
it is infectious



Practice Personal Safe Work Habits

- Wash hands before and after testing each client
- Change gloves for each client
- Wear lab coat or apron
- Dispose of lancets in designated container
- Do not retrieve anything out of the disposal container/bag



Practice Personal Safe Work Habits (Cont'd)

- Do not put pens/pencils in your mouth. It is *strictly forbidden*
- Never eat, drink, apply make-up, remove or insert contact lenses, or smoke at the test site
- Do not store food/drink in the QC sample refrigerator



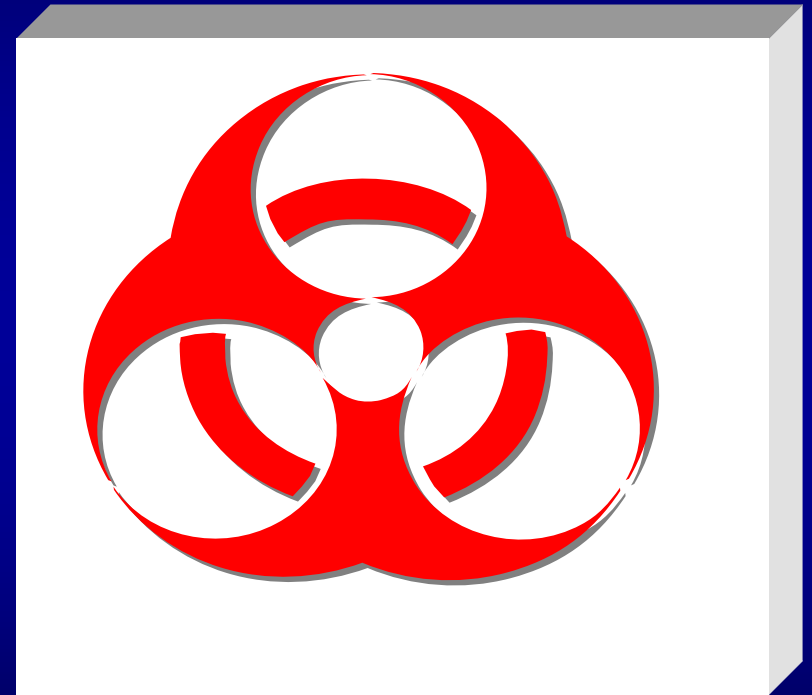
What is a Bio-Hazard?

An organism or substance capable of causing infection, disease or death.



Maintain Clean & Orderly Work Space

- Keep work areas uncluttered and clean
- Restrict or limit access when working
- Keep supplies locked in a safe and secure area



Biohazard



Drop Used Lancets in Special Containers



Lab workers



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Counselors

Disinfect Work Areas with Bleach

Disinfection

- Kills germs and pathogens
- Keeps work surface clean
- Prevents cross-contamination
- Reduces risks of infection



Different Cleaning Jobs Require Different Bleach Solutions*

General lab use - *Hypochlorite Solutions*

| Spills | General Disinfection |
|---------------------------|---------------------------|
| 10% (1 part + 9 parts) | 1% (1 part + 99 parts) |

You should have 10% bleach readily available at your test site.

* WHO Laboratory Biosafety Manual



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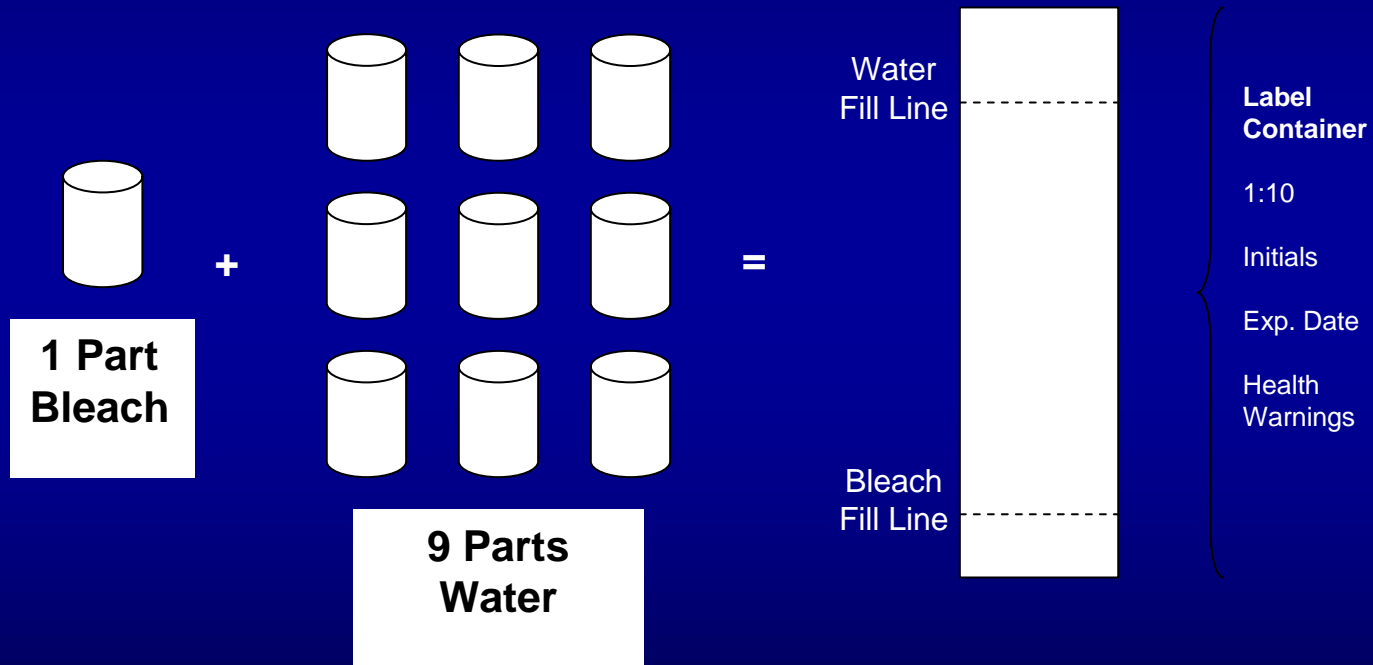
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Making a 10% Bleach Solution

Referred to as a 1/10, 1:10



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In Case of a Spill or Splash

- Wear clean disposable gloves
- **Large spills-** Cover with paper towels and soak with 10% household bleach and allow to stand for at least 5 minutes
- **Small spill** - Wipe with paper towel soaked in 10% bleach
- Discard contaminated towels in infectious waste containers



Incineration of Waste

- Incineration is burning of contaminated waste to destroy and kill micro-organisms.
- Incineration:
 - Prevents re-use
 - Protects environment
 - Must be conducted by authorized institutions



In Case of an Accident

What should you do?

- Assess & take action
- Report to manager immediately
- Record on standard form



Action Plan for Implementing Safety Practices

- Identify hazards
- Establish safety policies
- Implement safety procedures
- Keep proper safety records



ISO/TC 212

Secretariat: ANSI

Voting begins on:
2003-05-15

Voting terminates on:
2003-07-15

Medical laboratories — Requirements for safety

Laboratoires de médecine — Exigences pour la sécurité

Please see the administrative notes on page III

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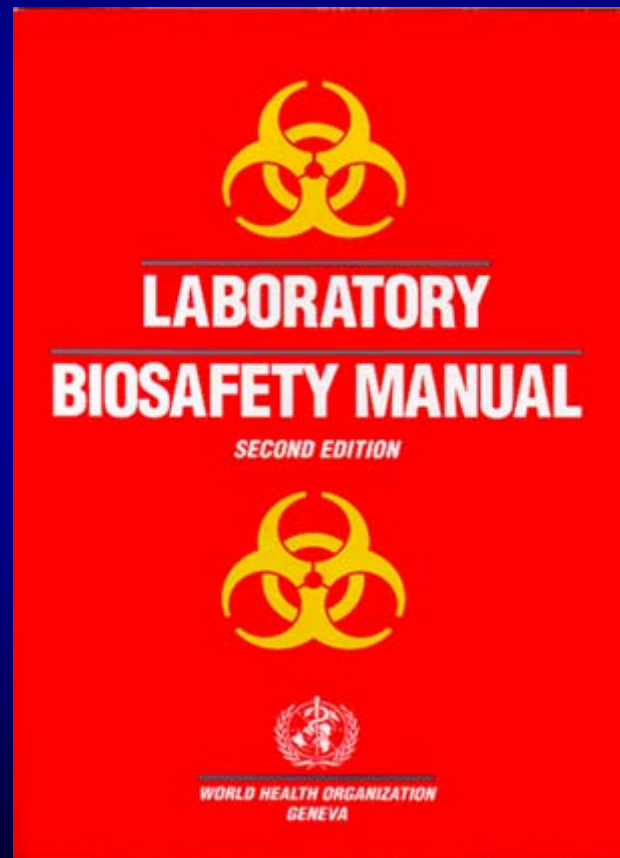
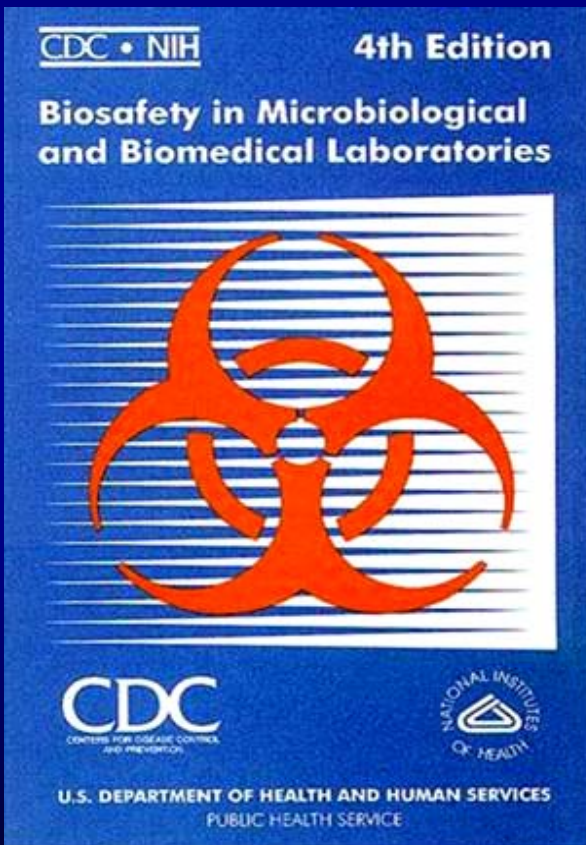


Reference number
ISO/FDIS 15190:2003(E)

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Safety References



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Module 7:

Preparing for Testing – Supplies and Kits



Learning Objectives

At the end of this module, you will be able to:

- List and identify all the supplies required for HIV rapid testing
- List and identify all the components of test kits for HIV rapid testing



Memory Game: Supplies & Materials

How To Play:

- Spend 3 minute browsing through the display and learn the items
- Spend 1 minute writing down as many items as possible (without looking)
 - Tally up the number of items you list
 - The person with the most items wins.



Materials & Supplies Checklist (Part 1)

- HIV rapid test kits
- Alcohol swabs
- Cotton
- Retractable Lancets
- Leak-proof bag for waste incineration
- Disinfectant
- Pen for writing
- Pen for labeling
- Timer or watch with minute hand
- Paper towels (for cleaning, hand washing and work area)
- Soap for hand washing



Materials & Supplies Checklist (Part 2)

- One positive QC sample
- One negative QC sample
- QC sample log
- Standard Operating Procedures
- Band Aids / plasters
- Thermometers
- Register for recording results



Gloves



- Single use disposable gloves
- Latex or polypropylene
- Without evidence of holes or tearing



Lab workers



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Alcohol



Lab workers

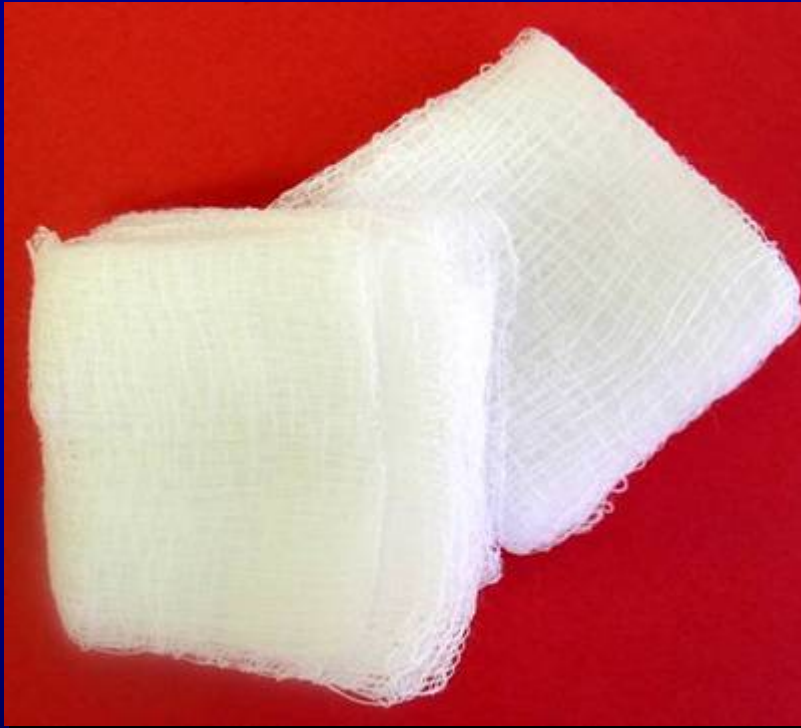


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Cotton Gauze or Cotton Balls



Single-use, hazardous waste disposal



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Retractable Safety Lancets



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Timers



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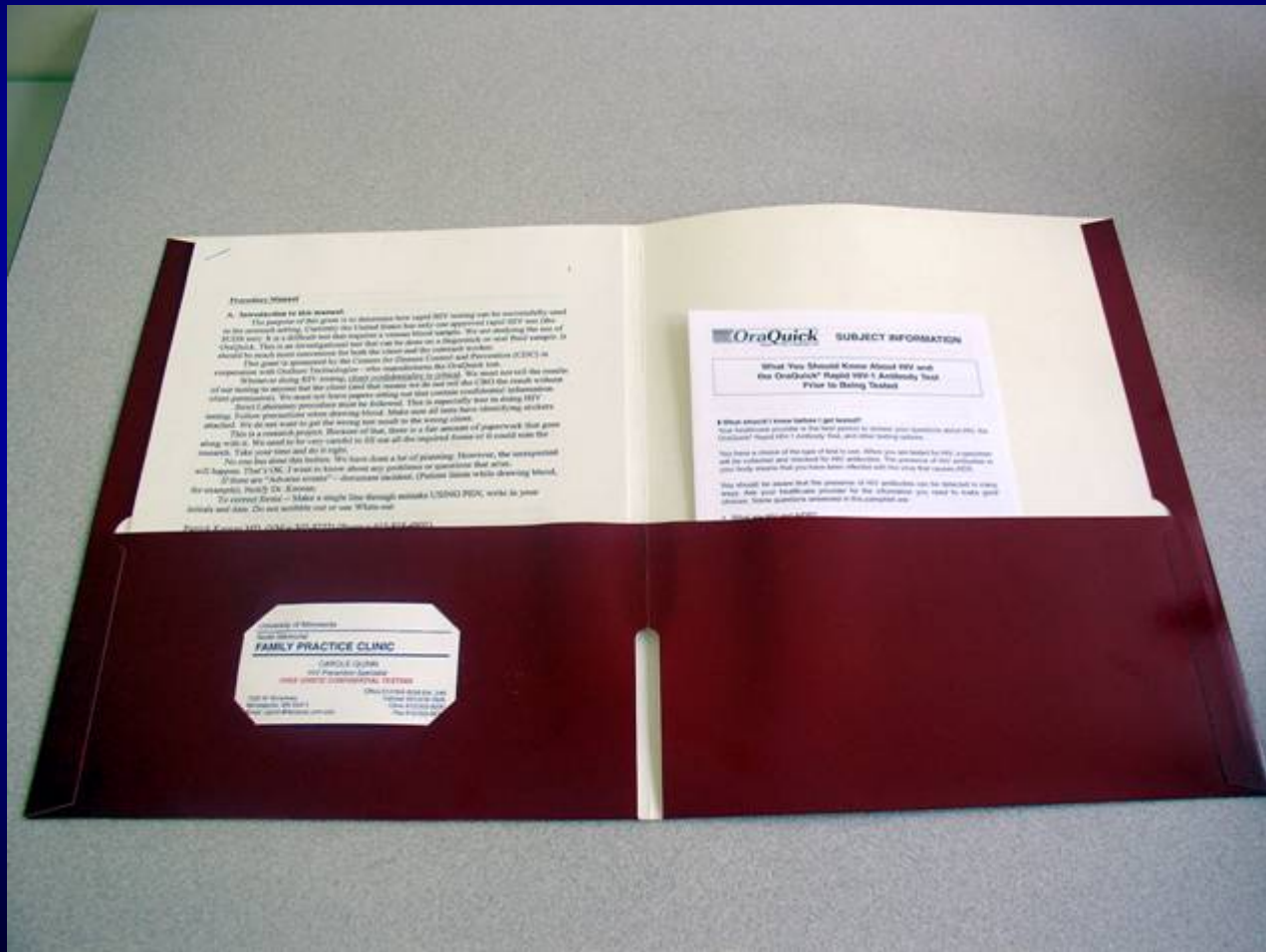


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Standard Operating Procedures and Forms



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Labeling Pens and Writing Pens

- Labeling Pens



- Writing Pens



Lab workers



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Counselors

Waste Disposal



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Examine Test Kits

- Display test kits used in-country
- Examine the different components found in each of the Rapid Test kits:
 - Desiccant packet – This is not used when performing the test.
 - Buffer solution – Required for whole blood testing.
 - Transfer pipette or loop
 - Testing device



Organize Your Work Area



Lab workers



Health workers



Counselors

Summary

- What type of lancets will be used for MOH TT “same-visit” testing?
- What are desiccant packs used for?
- What type of bag is needed for waste disposal?
- Which kit uses a loop for sample collection?
- How many QC samples are needed?



Module 8:

Blood Collection – Finger Puncture



Learning Objectives

At the end of this session you will be able to:

- Apply the principle of the finger puncture
- Select the appropriate finger for the procedure
- Perform and collect finger puncture blood accurately and confidently



Content Overview

- Preparing for testing
- Educating your client
- Performing a finger puncture



Puncture Site Selection

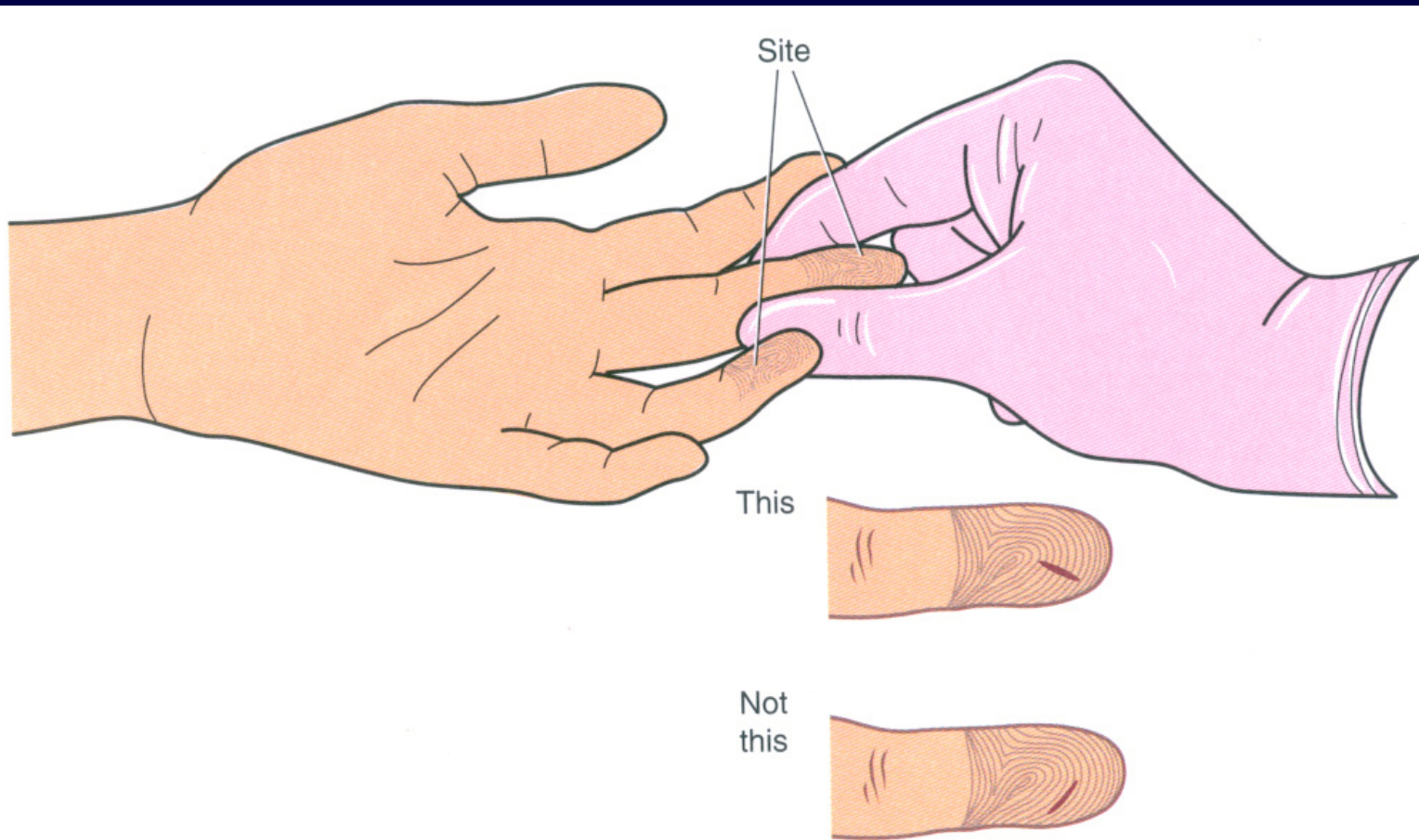
Finger selection:

- Middle finger or Ring finger

Area of finger:

- Central fleshy portion of the finger, slightly to the side of the centre and perpendicular to the whorls of the fingerprint





■ FIGURE 10-9 ■

Recommended site and direction of finger puncture.



Lab workers



Health workers



Counselors

Don'ts of Finger Puncture

- Do not puncture the side or the tip of the finger
- Do not puncture parallel to the grooves of the fingerprint
- Do not puncture the index finger
- Do not puncture the little finger
- Do not puncture the fingers of infants or very young children



Finger Puncture Procedure



Lab workers



Health workers



Counselors

Finger Puncture – Getting Started



1. Collect supplies



Lab workers



Health workers



Counselors

Finger Puncture – Finger Preparation



1. Choose whichever finger is least calloused.



2. Massage finger to increase blood flow.



3. Clean the fingertip with alcohol. Work from the middle out to reduce contamination. Allow the area to dry.



4. Grasp the finger and place a new sterile lancet on the side of the fingertip.



Lab workers

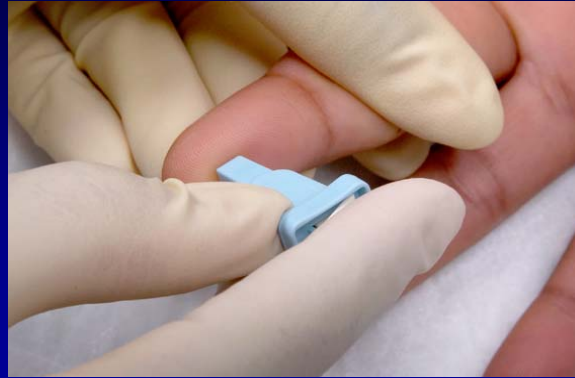


Health workers



Counselors

Finger Puncture – Collecting Blood



5. Firmly press the lancet to puncture the fingertip



6. Collect the sample. Blood may flow best when the finger is held lower than the elbow.



7. Apply a gauze pad or cotton ball to the puncture site until the bleeding stops



Lab workers



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Finger Puncture - Proper Disposal



8. Properly dispose of all contaminated supplies



Lab workers



Health workers



Counselors

Instructor-Led Demonstration



Lab workers



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Summary

- How do you put a client at ease while collecting blood?
- What supplies do you need for a finger puncture?
- What are the steps when performing a finger puncture?
- What safety precautions should you follow?



Module 9: Performing HIV Rapid Tests

Demonstration and Practice



Learning Objectives

- At the end of this module, you will be able to:
 - Define “Standard Operating Procedure” (SOP)
 - Perform MOH TT algorithm tests according to SOPs
 - Uni-Gold
 - Determine
 - Stat-Pak
 - Perform two tests simultaneously
 - Accurately interpret individual test results
 - Accurately determine HIV status



Content Overview

Overview of Testing Procedures

Workspace Setup

Demo + Practice
(individual tests on
known samples)

Video Presentation
and Discussion

Practice
MOH TT algorithm with
blood and/or plasma samples



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Predictive Value: Single HIV Test

Test Specificity 99.8%

| <u>HIV Prevalence</u> | <u>True +</u> | <u>False +</u> | <u>Positive Predictive Value</u> |
|---------------------------|---------------|----------------|--------------------------------------|
| 10% | 100 | 2 | 98% |
| 5% | 50 | 2 | 96% |
| 2% | 20 | 2 | 91% |
| 1% | 10 | 2 | 83% |
| 0.5% | 5 | 2 | 71% |
| 0.2% | 2 | 2 | 50% |
| 01.% | 1 | 2 | 33% |



Determine



Lab workers



Health workers



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Determine: Getting Ready



1. Collect test items



2. Use 1 strip per test
Preserve the lot number



3. Label the test strip with
client identification number



4. Remove protective foil cover



Lab workers

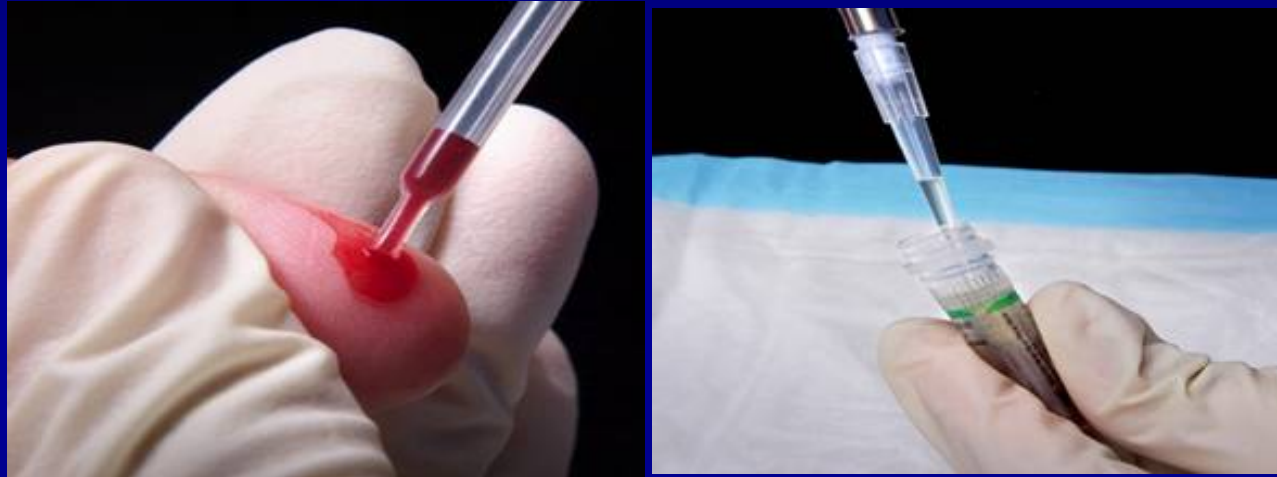


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Determine: Collecting Specimen



5. Collect 1 drop of blood using a plastic transfer pipette



Lab workers

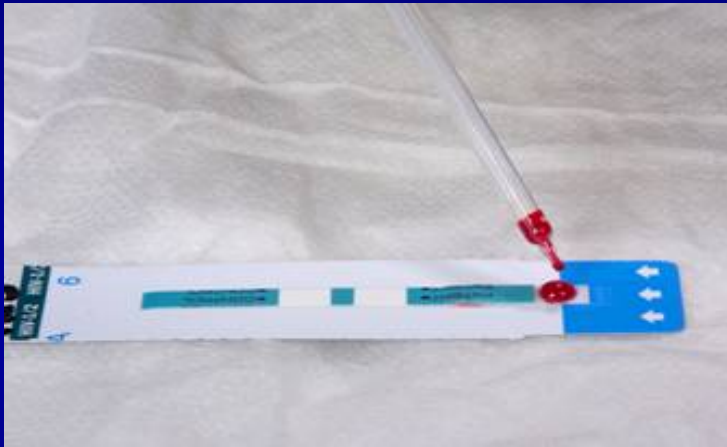


Health workers



Counselors

Determine: Applying Sample and Buffer to Test Strip



6. Apply the sample to the absorbent pad on the strip



7. Add 1 drop of chase buffer to the specimen pad



Lab workers



Health workers



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Determine: Getting Results



8. Wait 15 minutes before reading the results



9. Read and record the results



Lab workers



Health workers



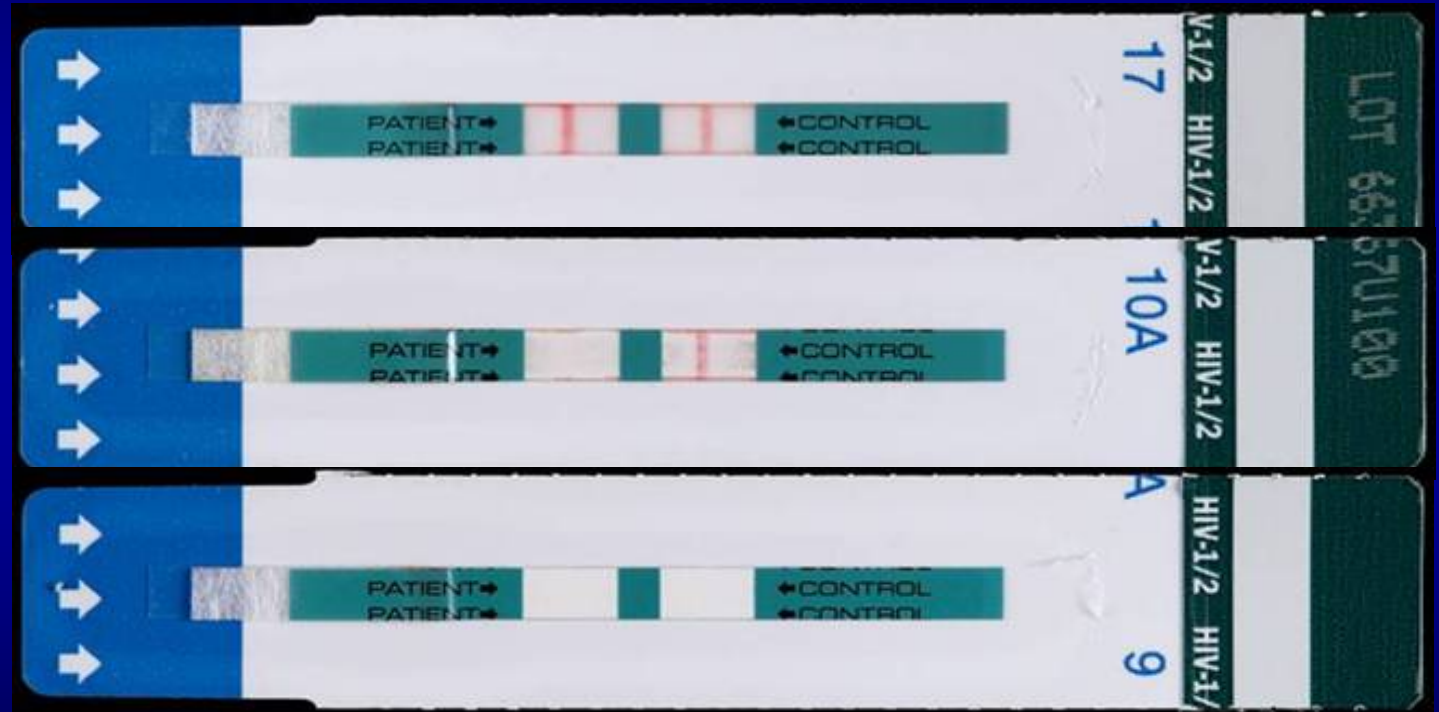
Counselors

Determine - Test Interpretation

Positive

Negative

Invalid



Lab workers



Health workers



Counselors

Uni-Gold



Lab workers



Health workers



Counselors

Uni-Gold: Getting Ready



1. Collect test items



2. Remove device from package and label it



Lab workers

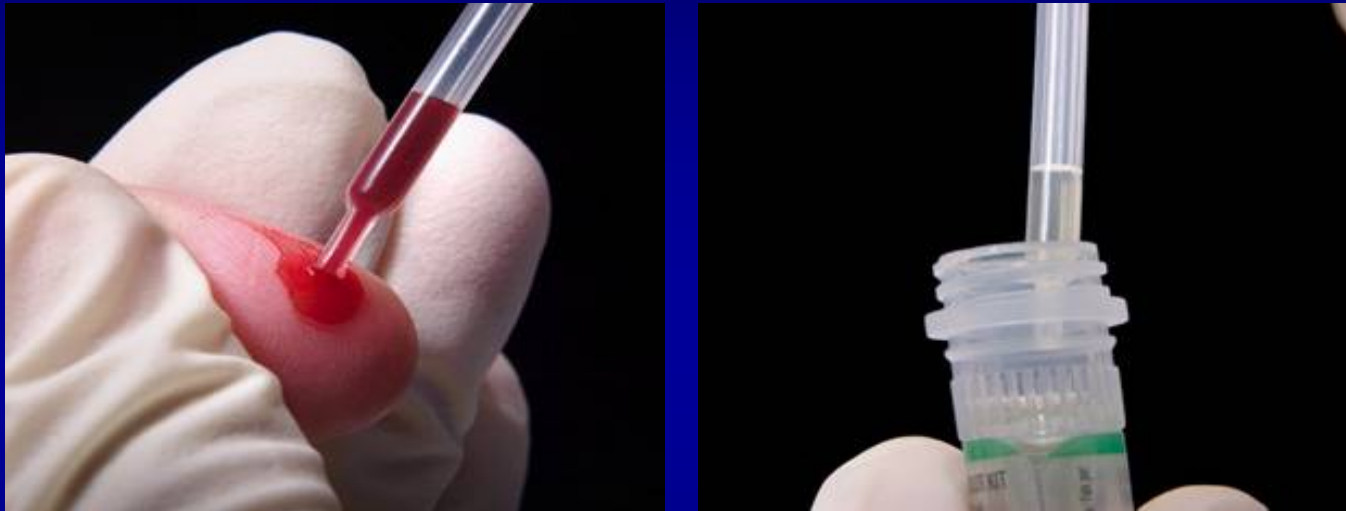


Health workers



Counselors

Uni-Gold: Collecting Specimen



3. Collect specimen using the disposable pipette



Lab workers



Health workers



Counselors

Uni-Gold: Adding Sample and Reagent to Test Device



4. Add 2 drops of sample to the sample port



5. Add 2 drops of wash buffer to sample port



Lab workers



Health workers



Counselors

Uni-Gold: Getting Results



6. Wait for 10 minutes to read the results



7. Read and record the results



Lab workers



Health workers



Counselors

Uni-Gold: Test Interpretation

Positive



Negative



Invalid



Lab workers



Health workers



Counselors

Stat-Pak



Lab workers

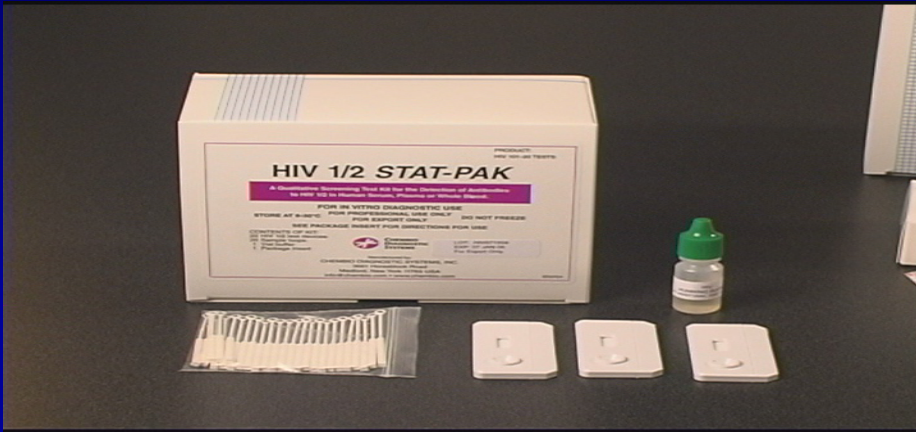


Health workers



Counselors

Stat-Pak: Getting Ready



1. Collect test items



2. Remove device from package and label it



Lab workers



Health workers



Counselors

Stat-Pak: Collecting Specimen



3. Collect specimen using the calibrated loop



Lab workers

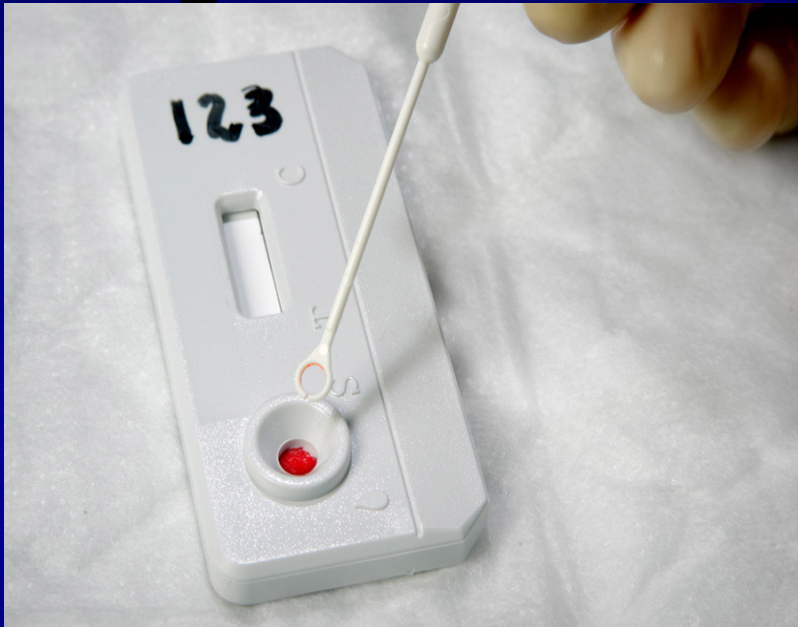


Health workers



Counselors

Stat-Pak: Adding Specimen and Reagent to Test Device



**4. Add sample to center of
SAMPLE well.**



**5. Add 3 drops of buffer. Drop
buffer directly over SAMPLE well.**



Lab workers



Health workers



Counselors

Stat-Pak: Getting Results

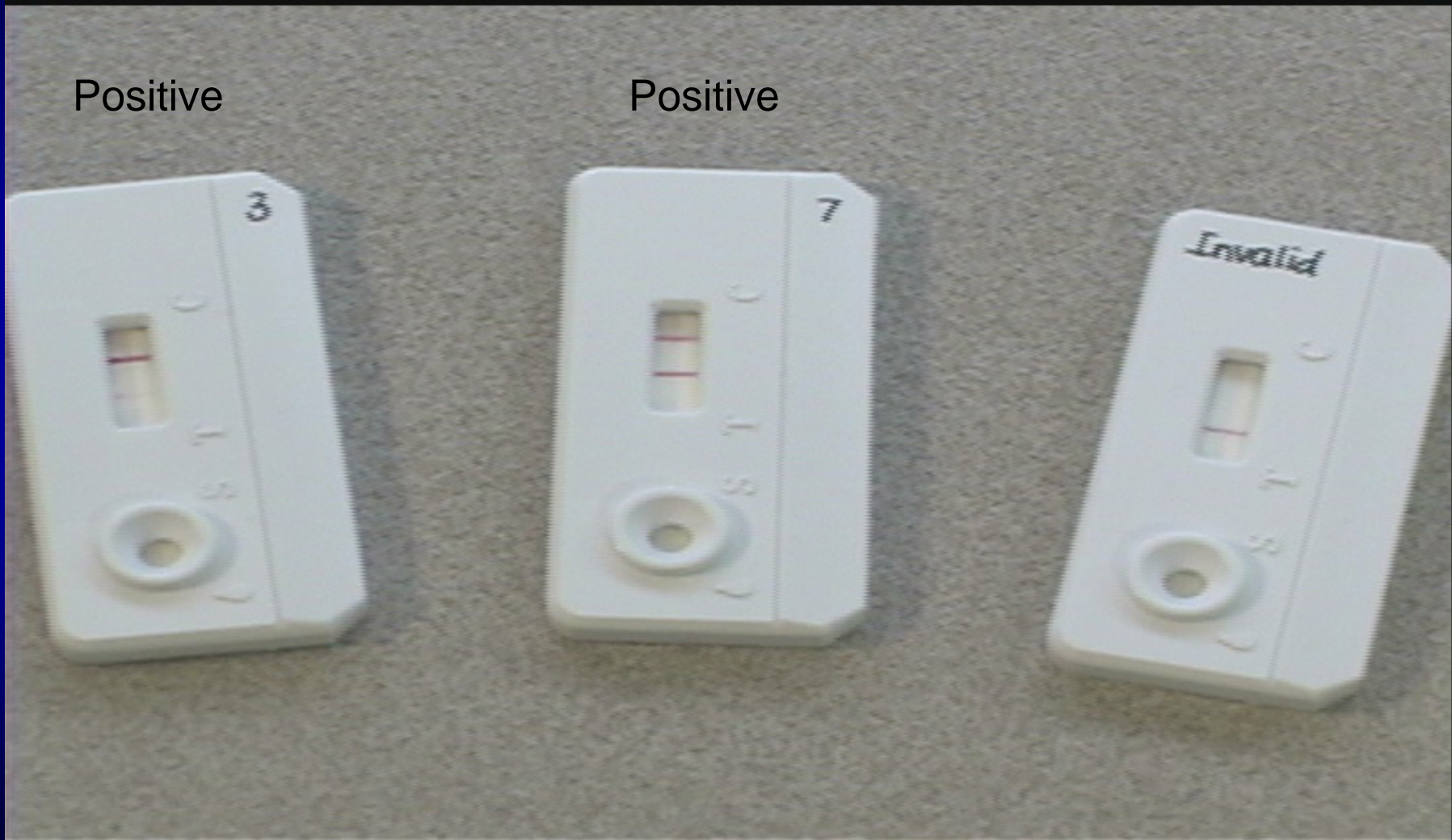


6. Wait for 10 minutes to read the results



7. Read and record the results

Stat-Pak: Test Interpretation



Lab workers



Health workers



Counselors

Stat-Pak: Test Interpretation

Positive



Lines of any intensity in **both** control and test areas.

Negative



Line in control area only.

Invalid



No line in control area.
Do not report invalid results.



Lab workers



Health workers



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Activity: Workspace Setup

- Identify your workspace
- Gather test kits and supplies
- Obtain positive and negative samples from instructor
- Arrange all items at your work station
- Activity time: 10 minutes



Hands-On Practice: Individual Tests

Instructions:

- Use safety precautions
- Practice with samples provided by your instructor only
- Raise your hand if you need additional supplies
- Show your test results to instructor after you are done

Total time: 15 minutes per test



Video Presentation and Discussion



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Counselors

Video: Determine

- What preparation is required before testing?
- What are the components in the test kit?
- What must you preserve when separating test strips from the packet?
- What information needs to be recorded, and where?
- How do you collect blood? What device do you use?
- How long do you set the timer?
- How many results are possible? How do you read them?



Video: Uni-Gold

- What preparation is required before testing?
- What are the components in the test kit?
- What information needs to be recorded, and where?
- How do you collect blood? What device do you use?
- How long do you set the timer?
- How many results are possible? How do you read them?

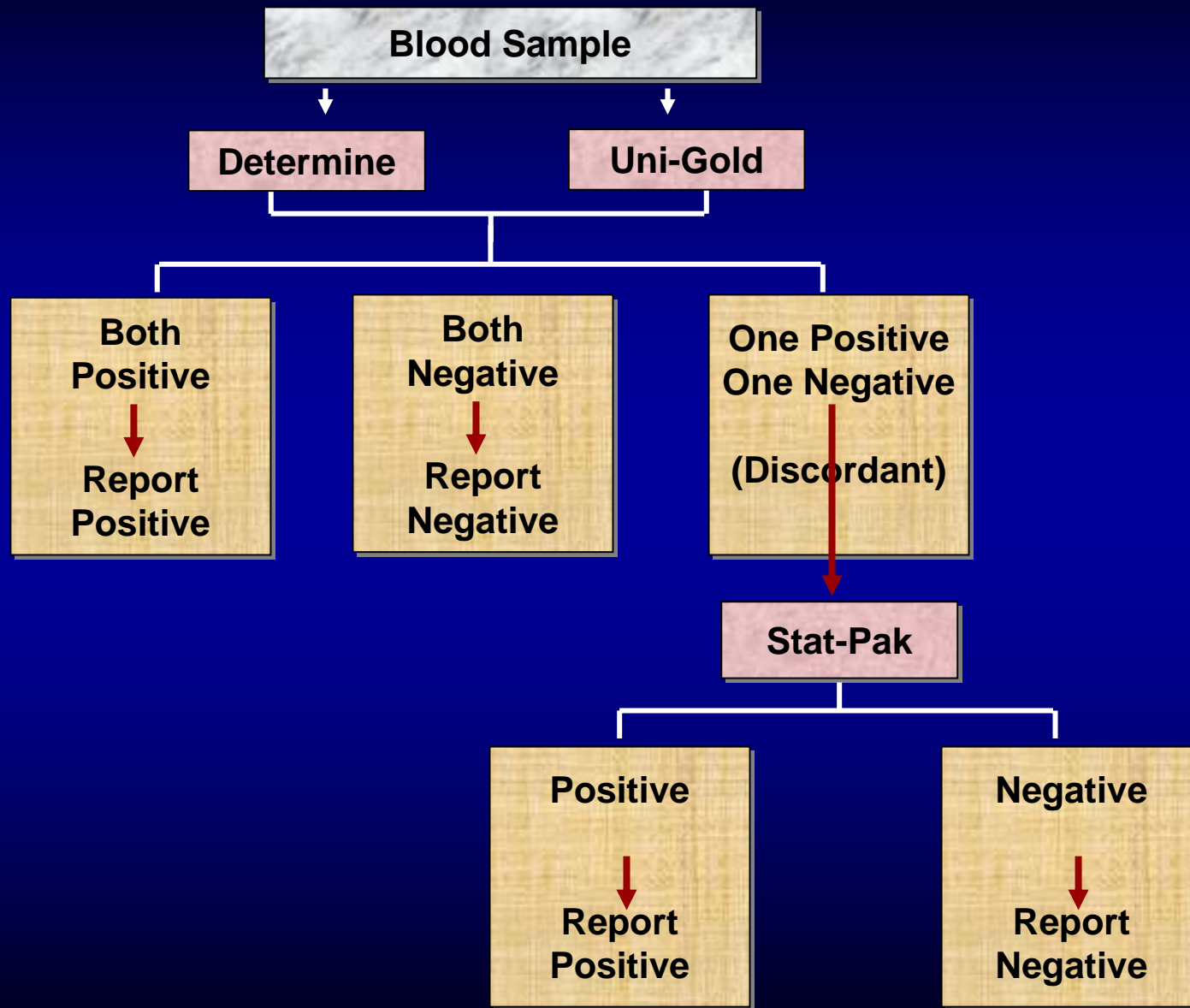


Video: Multiple HIV Tests

- Why must you keep two test kits separate when performing both at the same time?
- Do you collect blood at the same time or separately when performing multiple tests?
- How do you set the timer when two tests require different wait time?
- When is the third test used?
- How does it determine HIV status?



MOH TT Algorithm



Lab workers



Health workers



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Possible Outcomes in Parallel Algorithms

| TEST 1 | TEST 2 | TEST 3 | HIV Status |
|----------|----------|----------|------------|
| Negative | Negative | | Negative |
| Positive | Positive | | Positive |
| Negative | Positive | Negative | Negative |
| Positive | Negative | Negative | Negative |
| Negative | Positive | Positive | Positive |
| Positive | Negative | Positive | Positive |



Hands-On Practice: Parallel Algorithm

Conduct Determine, Uni-Gold and Stat-Pak tests simultaneously following the SOPs. Record the HIV status of each sample.

Specimen



Hands-On Practice: Parallel Algorithm

- Collect supplies
- Obtain panel of blind specimens
- Organize your workspace
- Complete one algorithm before starting the next
 - Use safety precautions
 - Practice only on samples provided
 - Raise your hand for additional supplies
- Record results on worksheet
- Do not discard test devices - instructor will check results



Summary

- Describe the key learning from performing:
 - (Uni-Gold)
 - (Determine)
 - (Stat-Pak)
- Describe the key learning from performing the multi-test algorithm

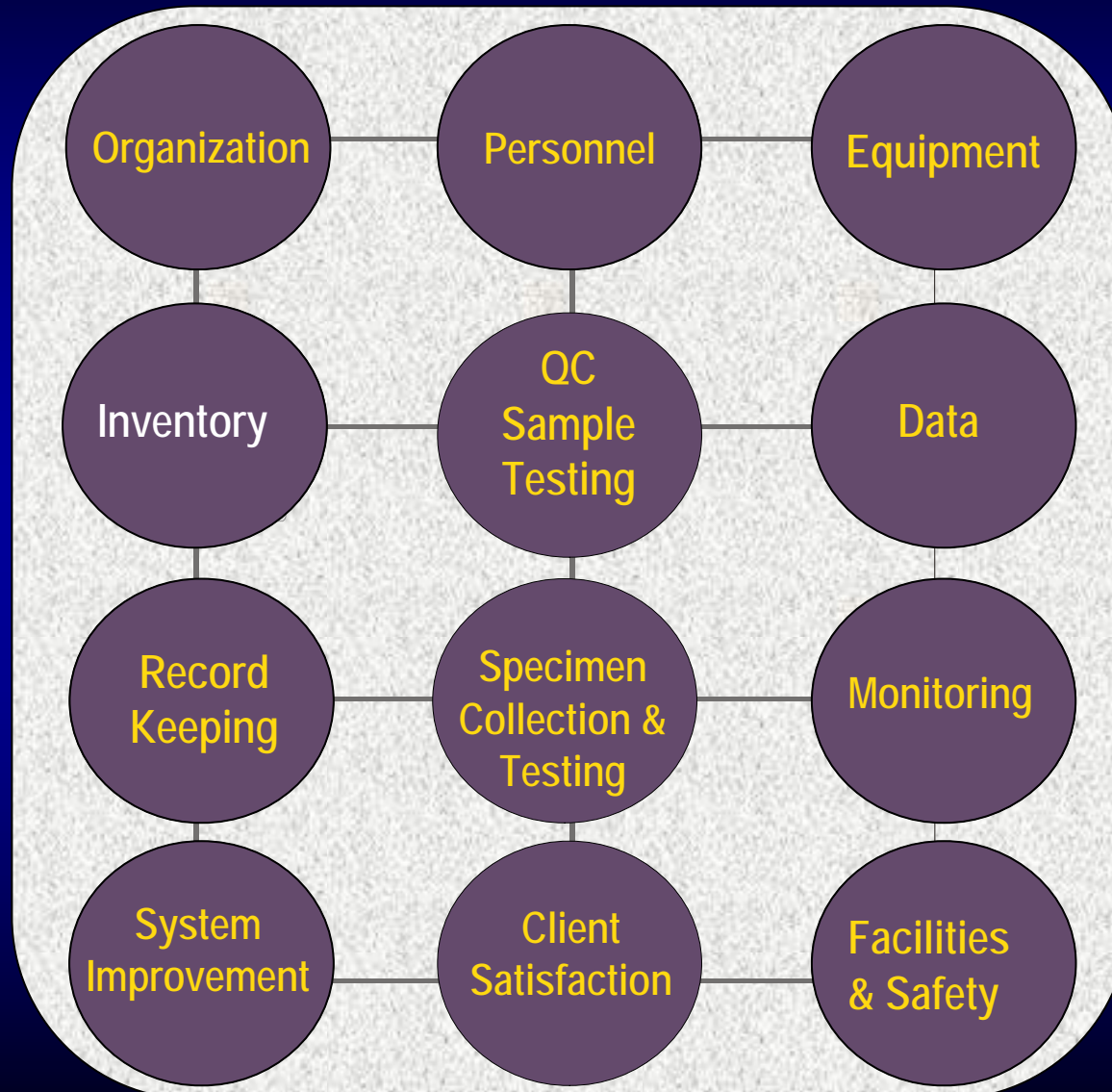


Module 10: Inventory

Managing Stock at the HIV Rapid Testing Site



Quality HIV Testing System



Lab workers



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Learning Objectives

At the end of this module, you will be able to:

- Maintain proper records
- Maintain proper level of consumables
- Use first-expiry-first-out concept when managing stock – Is “first in - first out” better?
- Inspect delivery of supplies before acceptance
- Identify lot numbers and expiry dates
- Store kits and supplies properly



Content Overview

What is stock management?

- Keeping record
- Re-ordering as needed
- Receiving consumables
- Storing consumables



Stock Management Means...

**Properly maintaining adequate
supplies to provide
uninterrupted service**



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Stock at Rapid Test Site Includes...

Inventory in Storage Area



and

Supplies at Workstation



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Stock Management Leads to High Quality Testing

- Guarantees availability of supplies
- Reduces costs
- Avoids the use of expired kits
- Reduces waste



How Do You Manage Stock?

You own a doubles cart. Your wife prepares the doubles you sell them for a profit. To make money, you must always have what your customers want.

What must you do to maintain adequate stocks?



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Stock Management Involves Knowing...

- What items you have.
- How many of each item you have.
- When to order.
- What you have ordered.
- How long it has been since you ordered.
- Where to store your stock.
- When new stock was received.
- Where new stock is located
- Who received the new stock.



Stock Management Involves...

- Performing a “stock count”
- Maintaining proper inventory records
- Determining when to re-order
- Determining how much to re-order
- Placing orders properly
- Inspecting delivery of new orders
- Storing stock properly



Perform a “Stock Count”

What is it? Counting each item in the stock

When is it done? Recommended at the beginning of each month

Who does it? A designated person

All items must be accounted for. Everything that comes in and goes out must be recorded.



Maintain Proper Inventory Records

Stock Card

- Simple, heavy weight cards
- Kept for each item in stock

Stock Book

- Contains listing of all items in the store
- Is updated after physical count
- Uses information from stock cards
- Is also called a Stock Register



Stock Card: An Example

- Item Name: _____ Unit: _____
- Manufacturer: _____
- Minimum Stock (Re-Order Level): _____

| Date | Received From | Issued to | Quantity Received | Quantity Issued | *Balance | Lot # | Signature |
|------|---------------|-----------|-------------------|-----------------|----------|-------|-----------|
| | | | | | | | |
| | | | | | | | |



Stock Book: An Example

| Item Name | Qty (units) Requested | Date Requested | Qty Received | Date Received | Lot # | Expiry Date |
|-----------|-----------------------|----------------|--------------|---------------|-------|-------------|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |



Reconciling Stock with Records

Ideal

Tests Performed = Stock Depletion

Reality

Test Performed + loss = Stock Depletion

What can be done to minimize loss?



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Decide When to Re-order

Re-order when stock reaches minimum level

Terminology:

- **Minimum stock** - Amount of stock required to support testing operations until additional supplies are received
- **Lead time** – Time between placing an order and receiving it
- **Maximum usage** – number of test kits used in a given time period



Calculating Minimum Stock Level

$$\text{Minimum Stock Level} = \text{Maximum lead time in weeks} \times \text{Maximum Usage}$$

Example:

Maximum lead time = 12 weeks

Maximum usage/wk = 3 kits

Minimum stock level = $12 \times 3 = 36$ kits

When only 36 kits are left, place an order



Exercise: Calculate Minimum Stock Level

$$\begin{array}{|c|} \hline \text{Minimum Stock} \\ \hline \text{Level} \\ \hline \end{array} = \begin{array}{|c|} \hline \text{Maximum lead time} \\ \hline \text{in weeks} \\ \hline \end{array} \times \begin{array}{|c|} \hline \text{Maximum} \\ \hline \text{Usage} \\ \hline \end{array}$$

- On average, you use 5 Uni-Gold kits a week.
- Usually you need 12 weeks to receive your orders.
- You should order more Uni-Gold kits when you have _____ kits left in the inventory.



Decide How Much to Re-order

Establish proper full stock level. Re-order to reach that level.

- **Review stock “use”. Include stock consumed, borrowed, expired, wasted, and pilfered.**
- **Never order more than you can store.**
- **Never order more than you can use before expiry.**
- **Know maximum usage AND minimum stock level**



Decide Full Stock Level

Maintain stocks that cover maximum usage plus minimum stock level

Maximum usage /wk = **70** tests
tests / month = **70 x 4**

280 tests used per month

Assuming 20 tests per kit, how many kits are used per month?

280 / 20 = 14

Lead time = 12 weeks (3 months)

Minimum stock level = 14 kits x 3 months = 42 kits

Full stock level = 42+14 = 56

You must have 56 kits in stock at the beginning of each re-order cycle.



Exercise: Decide Full Stock Level

Maximum usage /wk = 80 tests

How many tests are used per month?
_____ tests/month

Assuming 15 tests per kit, how many kits are used per month?

_____ kits/month

Lead time = 12 weeks or 3 months

Minimum stock level = _____ kits

Full stock level = _____ kits

You must always have _____ kits in stock at the beginning of each re-order cycle (3 months).

Calculate:

- What is the minimum stock level?
- How many test kits should you have in the beginning of each re-order cycle?



Place Orders Properly

- Describe current ordering system
- Provide instructions for placing orders
- Instruct trainees to complete forms needed for inventory/stock management.
- Describe contingency plan for stock shortages
- Describe communications to suppliers
 - Learn how to stop standing deliveries
 - Know how to request delivery
 - Know what information to tell central procurement



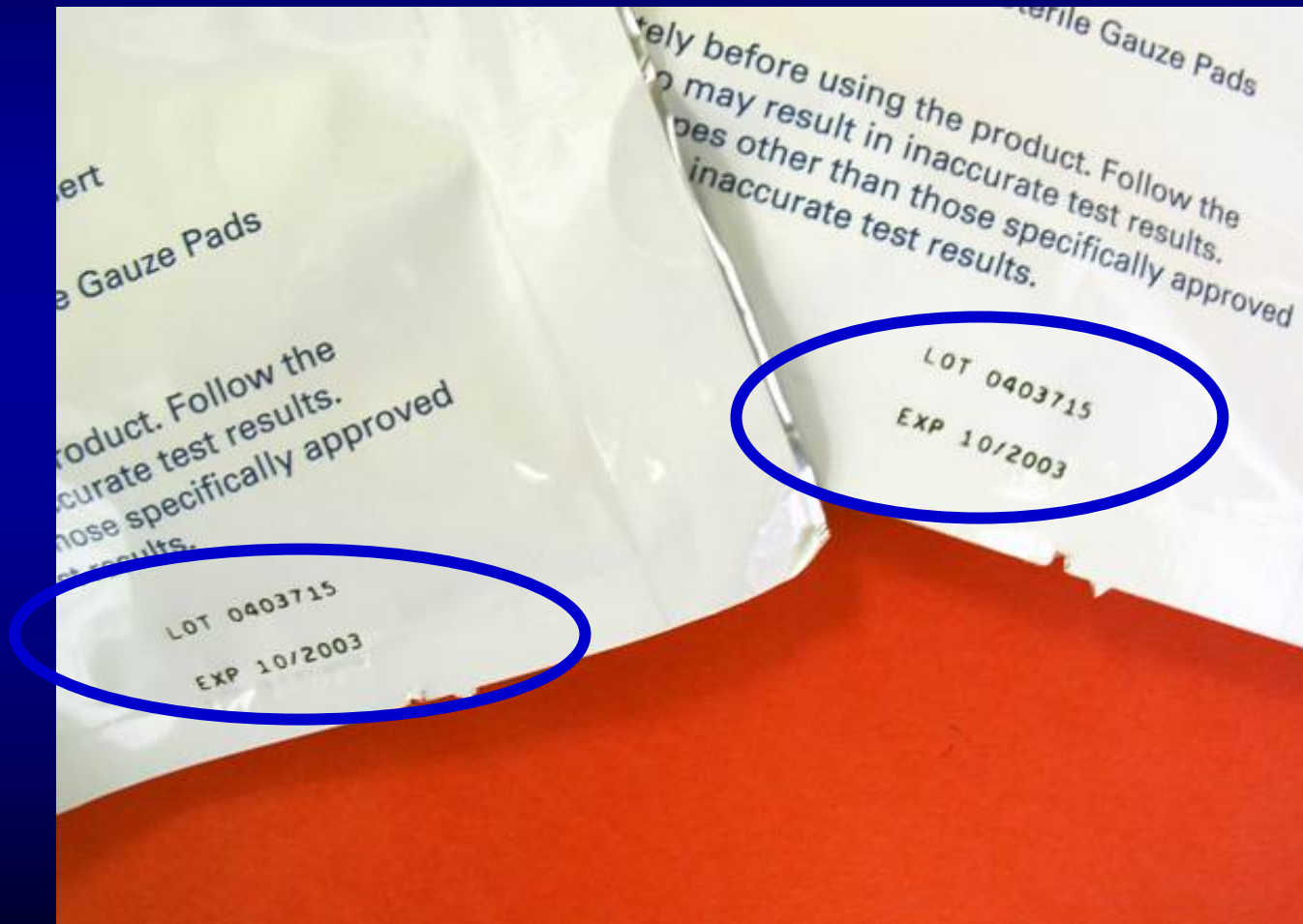
Inspect Delivery of New Orders

Upon receipt:

- Verify contents of order received with requisition
- Check integrity of received supplies
- Date each item received
- Note expiration date
- Store new shipment behind existing shipment
- Create or update records



Examine Lot Number & Expiry Date



Lab workers



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Counselors

Proper Storage of Stock

- Store stock in clean, organized, and locked storeroom
- Store in well-ventilated space away from direct sunlight
- Store according to manufacturer's instructions
- Record storeroom temperature daily
- Place items on shelves
- Organize existing and new shipments by expiration dates



First expiry, first out



Summary

- What does inventory management mean?
- What information is recorded in inventory record-keeping?
- How do you decide minimum stock level?
- How do you decide proper full inventory level?
- What does “First Expiry First Out” mean?
- What procedure should you follow when receiving new kits and supplies?
- How should kits and supplies be stored?



Key Messages

- Maintain adequate inventory at all times.
- Do not run out of anything before re-order.
- Never order more than you can store.
- Never order more than you can use before expiry.
- **NOTIFY OVERAGE-redistribute before expiry.**
- Account for all items in inventory.
- Inspect new shipments before acceptance.

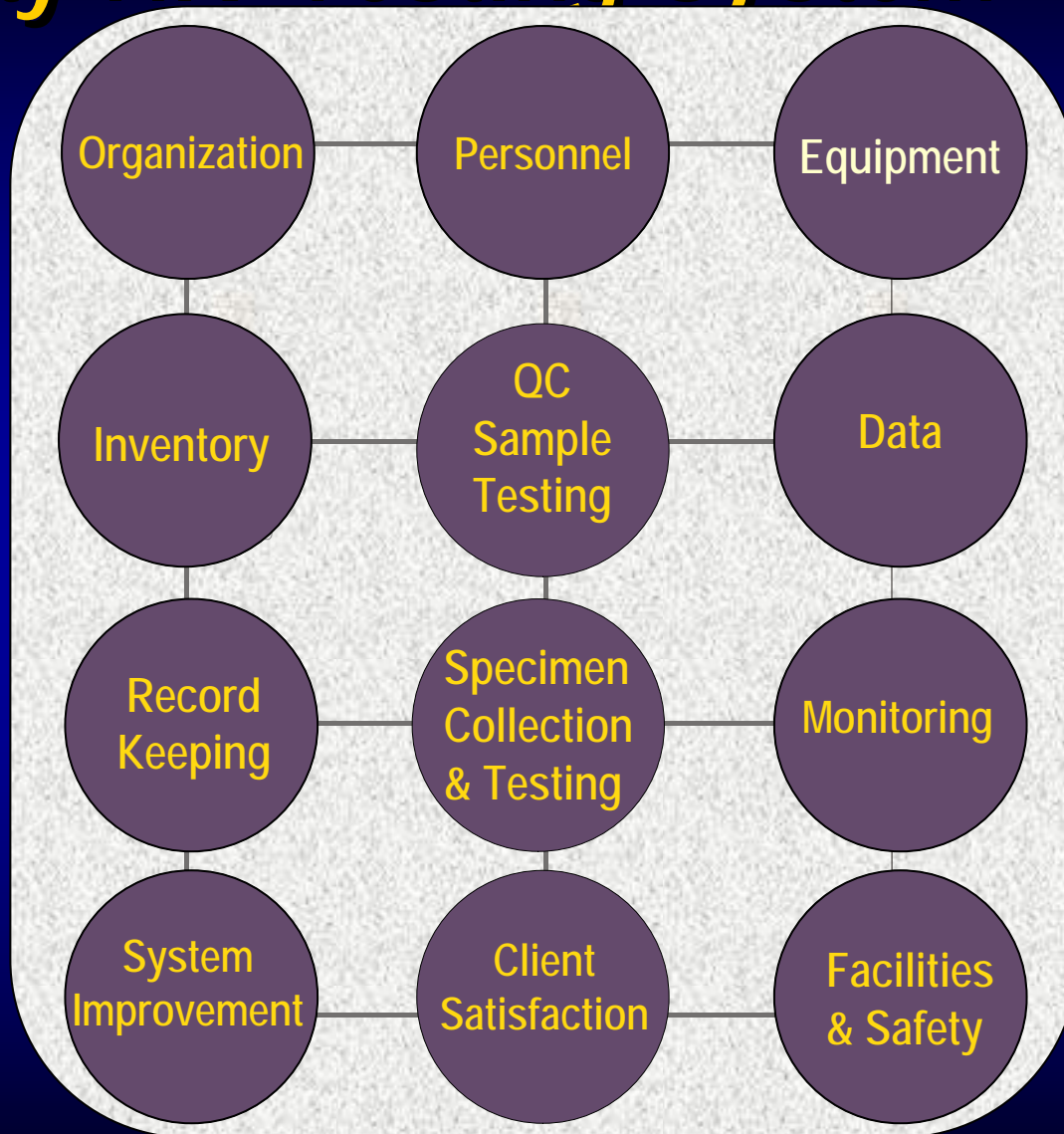


Module 11: Refrigerators

QC Sample Storage at HIV
Testing Sites



Quality HIV Testing System



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Learning Objectives

At the end of this module, you will be able to:

- Monitor temperatures
- Keep temperature records

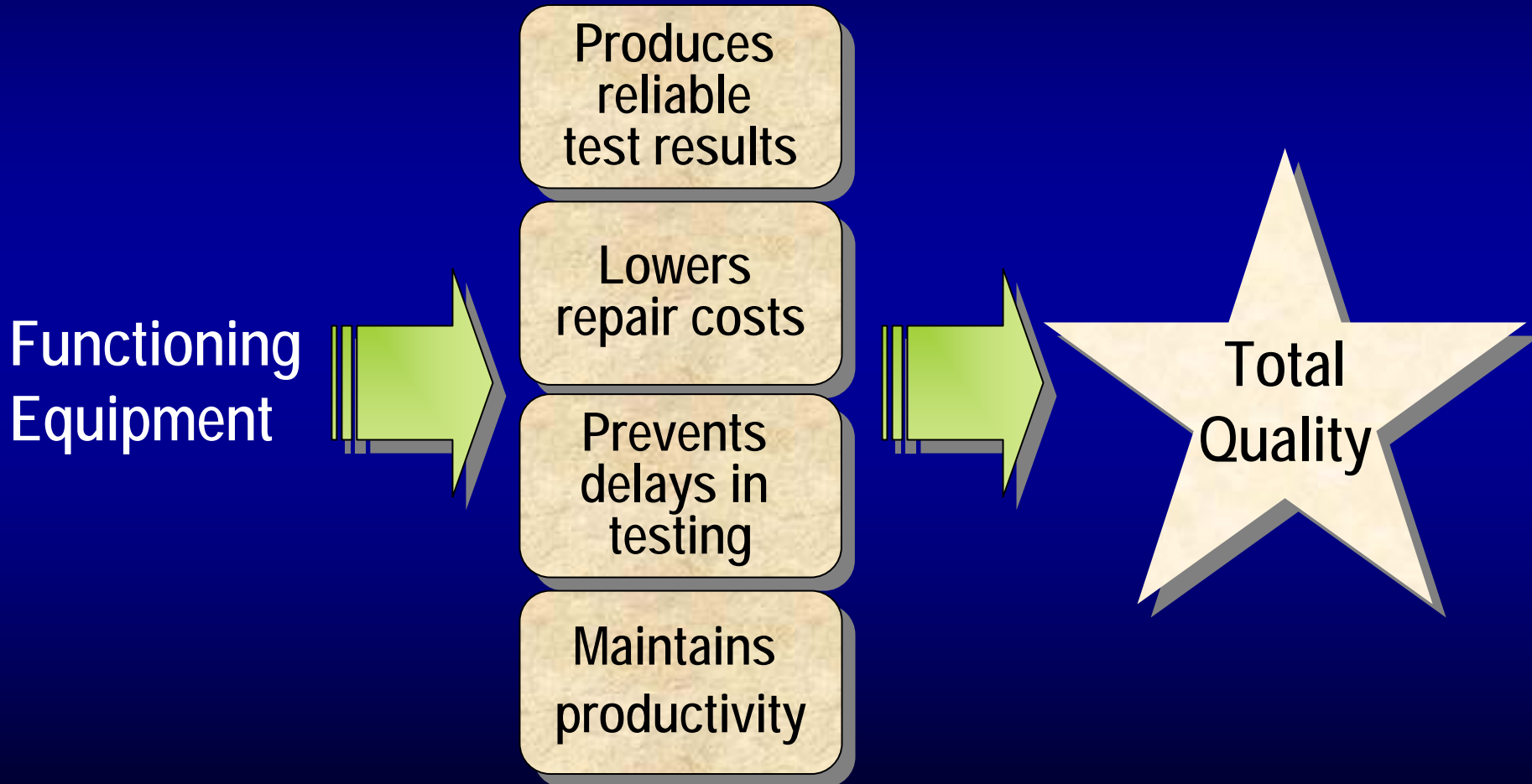


Content Overview

- Rationale for equipment maintenance
- Your responsibilities for equipment
- Refrigerators at HIV rapid testing sites



Functioning Equipment is Vital to Quality Service



Equipment at HIV Rapid Testing Sites

Refrigerator



Lab workers



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Counselors

Temperature Log

Manufacturer _____
Model No _____

Year _____

QS Sample Refrigerator Temperature Record

Range (2 to 8 °C)

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|-----|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Jan | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Apr | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Jun | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Dec | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |



Lab workers



Health workers



Counselors

Responsibilities at Test Site

- Record refrigerator temperatures (2°C to 8°C)
- Record storage area temperature (28°C or less)
- Record Testing room temperature (28°C or less)
- Report incorrect temperatures to your supervisor
- Take corrective actions
- Keep records for each day of testing



Stop testing
if refrigerator
fails!



Refrigerator Care

- Keep clean
- Close completely
- Report temperatures above 8°C or below 2°C
- DO NOT store food or beverages in the QC sample refrigerator



Summary

- Why keep temperature records?
- What is the proper temperature for the QC sample refrigerator?
- Why not store food in the QC refrigerator?
- What is the maximal permitted temperature for the storage area?
- What should you do when you record incorrect temperatures?



Module 12: Quality Control



Content Overview

- What is Quality Control (QC)?
- Benefits of QC in rapid testing
- Internal versus external quality control
- Troubleshooting invalid results
- Quality control records



What is Quality?



Lab workers



Health workers



Counselors

What Is Quality Control (QC)?

- Monitoring the quality of the test itself
- Reporting results that are correct



Controls for MOH TT HIV Rapid Testing

- Internal
 - Controls within the testing device
- External
 - Controls of *known* HIV status provided by an external source.



Internal and External Quality Control

Internal Control

Included in testing device



Control
Band

External Control

Known positive and negative samples used to check the testing process



Lab workers



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Counselors

External Quality Control Samples

**Prepared by
Reference
Laboratory**

**Commercially
prepared**

- Store according to instructions
- Date when opened
- Use before expiry date
- Do not contaminate



Use of External Control Samples in the MOH TT Testing System

- Each tester must test one positive and one negative control with each kit (Determine, Unigold and Stat-Pak):
 - At the start of each day of testing
 - At the beginning of a new lot number



Quality Control Record: An Example

QC SAMPLE LOG

| Date and Time | Tester | QC samples Lot # | Determine® | | | Uni-Gold™ | | | Stat-Pak | | |
|---------------|--------|------------------|------------|---------|--------|-----------|---------|--------|----------|---------|--------|
| | | | Lot # | Ex Date | Result | Lot # | Ex Date | Result | Lot # | Ex Date | Result |
| | | Pos | | | | | | | | | |
| | | Neg | | | | | | | | | |
| | | Pos | | | | | | | | | |
| | | Neg | | | | | | | | | |
| | | Pos | | | | | | | | | |
| | | Neg | | | | | | | | | |
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| | | Pos | | | | | | | | | |
| | | Neg | | | | | | | | | |
| | | Pos | | | | | | | | | |
| | | Neg | | | | | | | | | |



QC Invalid Results – What Do You Do?

- Repeat test
- If the second test is invalid, STOP testing for the day.
- Identify cause of problem
- Inform manager
- Take corrective actions



Troubleshooting Invalid Results

Problem

No control line or band present

Potential Cause

- Damaged test device or controls
- Proper procedure not followed
- Expired or improperly stored test kits or controls

Action

- Repeat the test using new device
- Follow each step of testing according to SOP
- Re-check buffer and/or specimen volumes
- Check expiry date of kits and QC samples. Do not use beyond stated expiry date
- Check temperature records for storage and testing area



Troubleshooting Invalid Results – Cont'd

Problem

Positive reaction with negative QC sample, i.e. false positive

Potential Cause

Mixed up samples

Action

Re-test negative control using a new device and read results within specified time limit

Extremely faint control line

The control line can vary in intensity

No action required. Any visible line validates the results.



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Exercise #1: Interpreting Rapid Test Results

- Read the test results from the teaching aids we have just handed out.
- Write your interpretation on the index card provided.



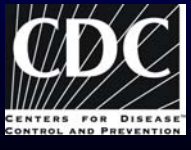
Review of Quality Control

- Review of internal control results before accepting test results
- Review of external control results by tester
- Regular review of QC sample logs and other records by the Quality Monitor (site audits)



Module 13: Quality Monitoring

On-site Review and Auditing



Content Overview

- What is quality monitoring?
- Why is it important?
- Who will provide quality monitoring for MOH TT “same visit” HIV testing?
- Test site records
- Internal and external audits
- Verification panels



Review of Quality Control

- Review of internal control results before accepting test results
- Review of external control results by tester
- Regular review of QC sample logs and other records by the Quality Monitor (site audits)

Quality Monitoring Definition

Objective review of testing by an external agency or personnel



Why Quality Monitoring?

- To compare performance and results among test sites
- To provide early warning for systematic problems in testing
- To evaluate quality of testing
- To stop testing when appropriate



Monitoring Where Testers are Counselors

- Client confidentiality is top priority
- Monitoring must be indirect
- Internal auditing is by tester
- Site auditing is by quality monitors
- Quality monitors will provide feedback *during* the site audit
- Quality monitors have authority to stop testing

MOH TT Monitoring Components

Temperature
Records

QC Sample Log

Testing Records

Verification
Panels



Supervisors or Managers



Testers

What is a Site Audit?

A site audit is review of the testing process to collect information needed for process improvement.

Site audits may be:

- Internal - conducted by the person who is performing testing
- External – conducted by the Quality Monitor



Components of Site Audit

- Review temperature records
- Review QC sample log
- Review client test result records
- Verify inventory control records
- Observe cleanliness of testing site
- Observe cleanliness of QC refrigerator
- Request tester to complete verification panel (external audit only)
- Discuss review observations with tester

Management Responsibilities:

- Establish quality monitoring policy
- Assign responsibilities
- Respect Quality Monitor and/or Tester decisions about testing
- Correct deficiencies
- Communicate outcomes to all involved



Summary

- Quality Monitors are responsible for site audits
- Quality Monitors have authority to stop testing
- Effective Site Managers will respect and support decisions made by the Tester and the Quality Monitor

Module 15:

Documents and Records

Learning to “Think like a lab person” (part 2)



Learning Objectives

At the end of this module, you will be able to:

- Explain differences between documents and records
- Explain the relationship between records and quality of testing
- List documents and records for quality testing at MOH TT testing sites
- Follow standard operating procedures (SOPs)
- Keep MOH TT testing site records accurately

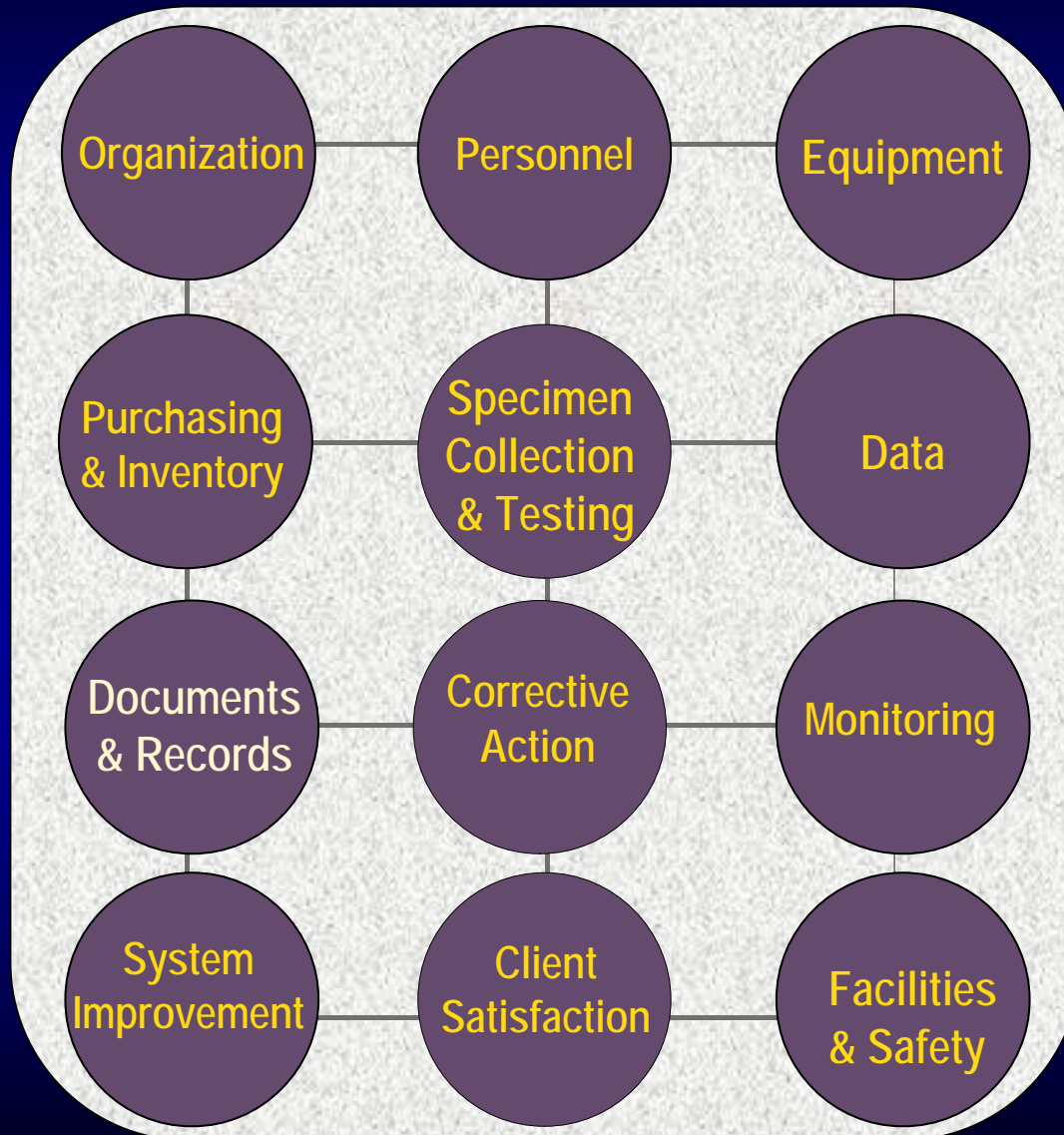


Content Overview

- What are documents and records?
- Documents
 - Why are they important?
 - What documents should you keep?
 - Why follow SOPs?
 - What is the proper way to keep and maintain documents?
- Records
 - Why are they important?
 - What records should you keep?
 - What is the proper way to keep and maintain records?



T&T Quality Health Care System



Lab workers



Health workers



Counselors

What Are Documents and Records?

Documents

- WRITTEN policies, process descriptions, procedures, and blank forms used to communicate information



Records

- Information on worksheets, forms, and charts (collected on documents)



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Which Is Which?

Documents and Records

- MOH TT testing algorithm
- Reference manual
- Temperature logs (completed)
- SOPs for individual HIV rapid tests
- Manufacturer product inserts
- Temperature logs (blank)
- QC sample log (blank)
- Inventory cards (completed)
- Client record (completed)
- Client record (blank)
- Summary of findings from a site audit



Which Is Which?

Documents and Records

- MOH TT testing algorithm
- Reference manual
- Temperature logs (completed)
- SOPs for individual HIV rapid tests
- Manufacturer product inserts
- Temperature logs (blank)
- Inventory cards (completed)
- QC sample log (blank)
- Client record (completed)
- Client record (blank)
- Summary of findings from a site audit

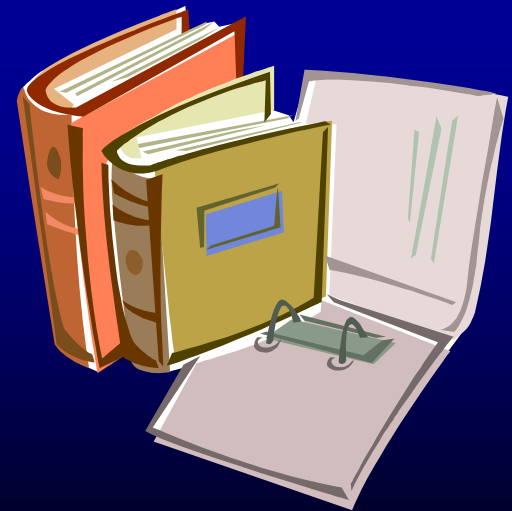


Documents Are the Backbone of the Quality System

Verbal instructions often are:

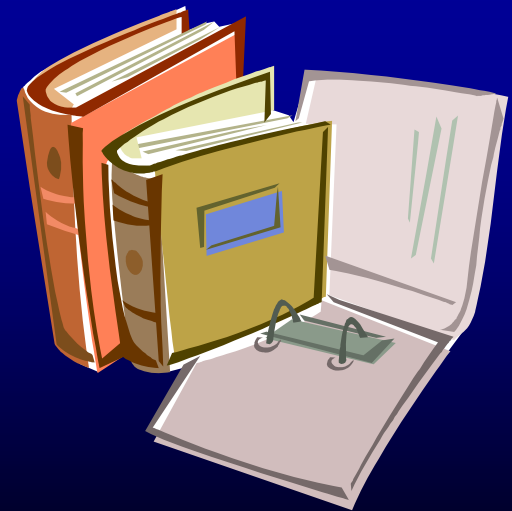
- Not heard
- Misunderstood
- Quickly forgotten
- Ignored

Policies, standards, processes, and procedures must be written down, approved, and communicated to all concerned.



Standard Operating Procedures (SOPs) Are Documents that...

- Describe how to perform various operations in a testing site
- Provide step-by-step instructions
- Assure:
 - Reliability
 - Accuracy
 - Quality



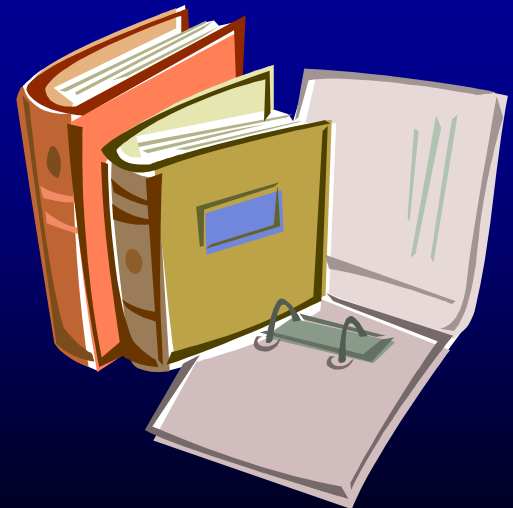
Use Test Site SOPs

- Manufacturer product inserts are not sufficient for testing.
- Test site SOPs include:
 - Materials required, but not in kit
 - Specific safety requirements
 - Sequence of tests for MOH TT testing
 - QC Samples testing procedure

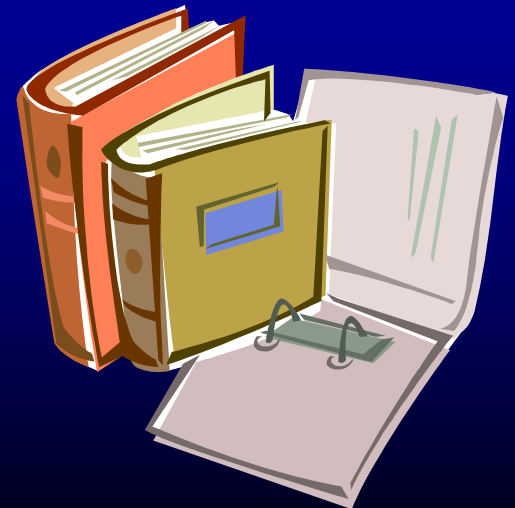


SOPs Must Be Followed

- Why is it important to follow SOPs?
- What happens if you do not?



MOH TT Documents



Lab workers



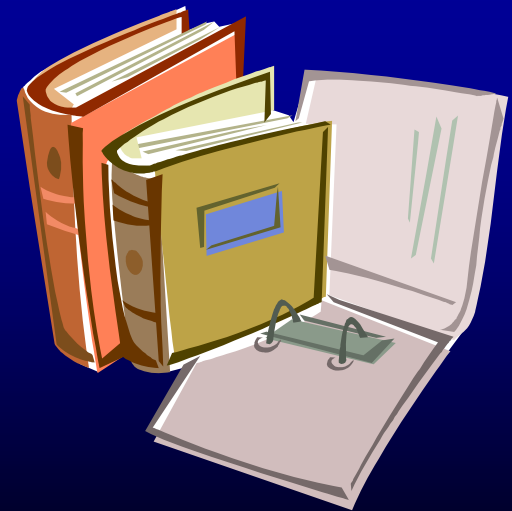
Health workers



Counselors

What Documents Are Needed at MOH TT Testing Sites?

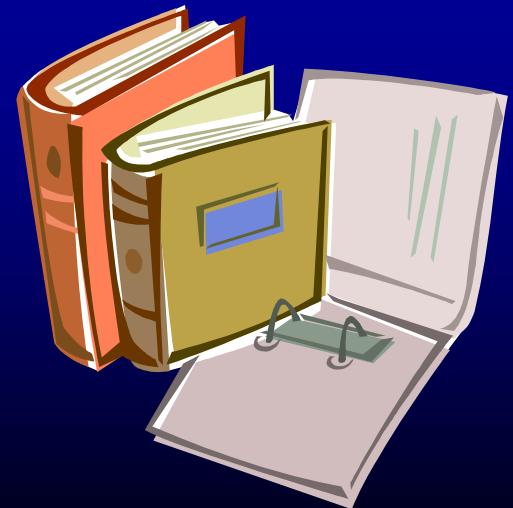
- MOH TT Testing Algorithm
- Temperature Logs
- Finger-stick blood draw procedure
- QC Sample Log
- Determine SOP
- Uni-Gold SOP
- Stat-Pak SOP
- HIV Test Report
- Inventory Cards



MOH TT Temperature Logs

Three Temperature Logs are needed at each MOH TT testing site:

- QC Sample Refrigerator
- Rapid Test Kit Storage Area
- Testing Area



MOH TT Temperature Logs

- Fill accurately
- Write legibly
- Date

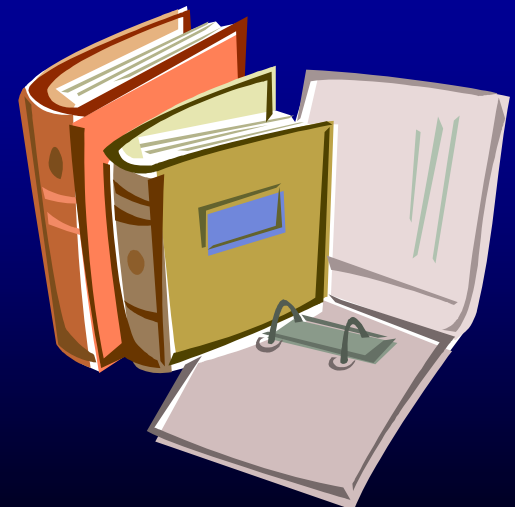
Manufacturer _____
Model No. _____

Year _____

QS Sample Refrigerator Temperature Record

Range (2 to 8 °C)

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|-----|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Jan | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Feb | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mar | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Apr | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| May | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Jun | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Jul | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Aug | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sep | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Oct | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Nov | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Dec | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |



Lab workers



Health workers



Counselors

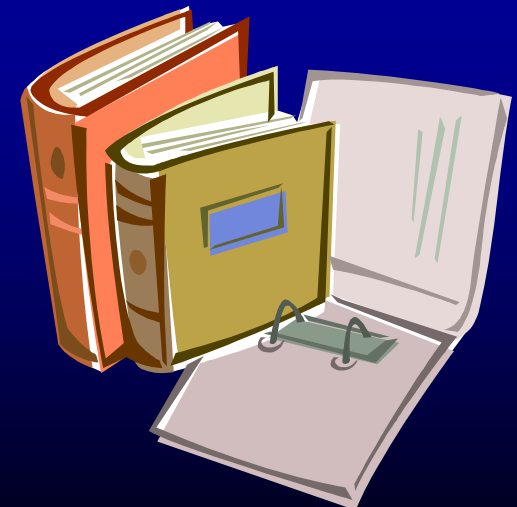
MOH TT Temperature Logs

Year _____

**Kit Storage
Temperature Record**
(less than 28 °C)

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|-----|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
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| Sep | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Oct | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Nov | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Dec | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

- Fill accurately
- Write legibly
- Date



Lab workers



Health workers



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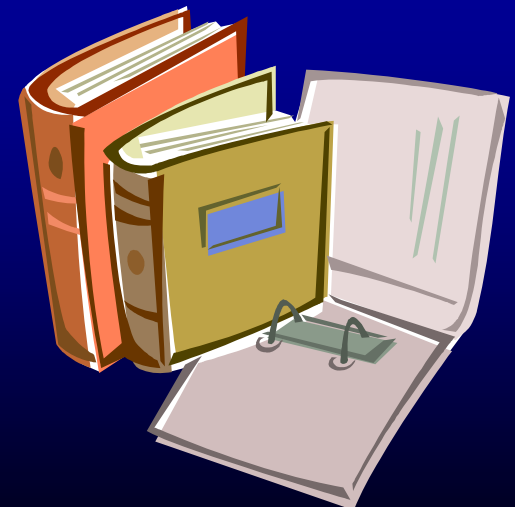
MOH TT Temperature Logs

Year _____

**Testing Area
Temperature Record**
(less than 28 °C)

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 |
|-----|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Jan | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Feb | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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- Fill accurately
- Write legibly
- Date



Lab workers



Health workers



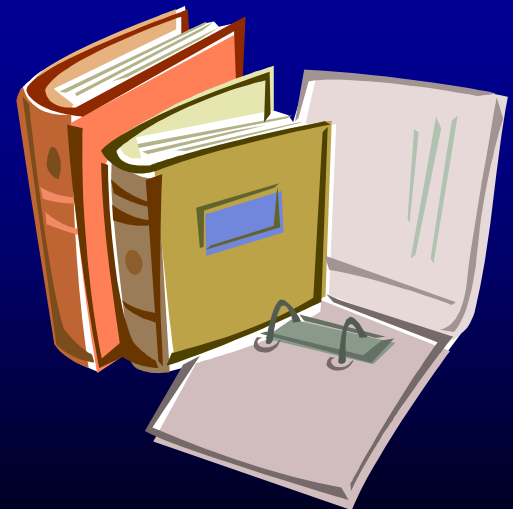
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MOH TT Blood Collection Procedure

Each client will be asked to provide a sample of blood for testing.

Each blood sample should be collected the same way.

Collection should follow the Finger-Stick Blood Draw SOP



MOH TT Blood Collection Procedure

Finger-Stick Blood Draw

Always use universal safety precautions



1. Collect supplies. Wear gloves.



2. Choose whichever finger is least calloused.



3. Massage the finger to increase blood to flow.



4. Clean fingertip with alcohol. Work from the middle out to reduce contamination. Allow the area to dry.



5. Grasp the finger and place a new sterile lancet on the side of the fingertip.



6. Firmly press the lancet to puncture the fingertip.



7. Collect the sample. Blood may flow best when finger is held lower than the elbow.



8. Apply a gauze pad or cotton ball to puncture site until bleeding stops.



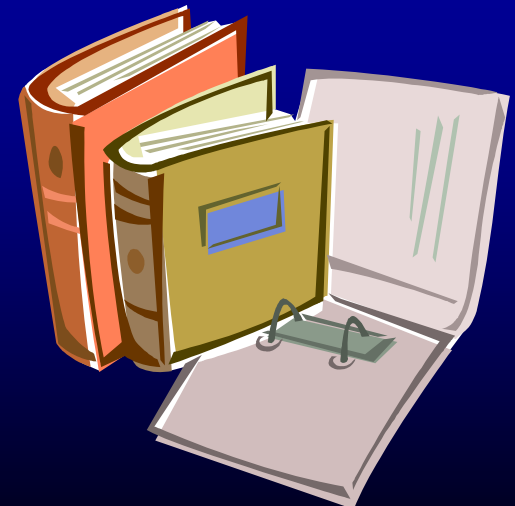
9. Properly dispose of all contaminated supplies.



Use of trade names and commercial sources is for identification only and does not imply endorsement by WHO, the Public Health Service, or by the U.S. Department of Health and Human Services (2009).



Blood collection from each client should follow the Finger Stick Blood Draw SOP



Lab workers



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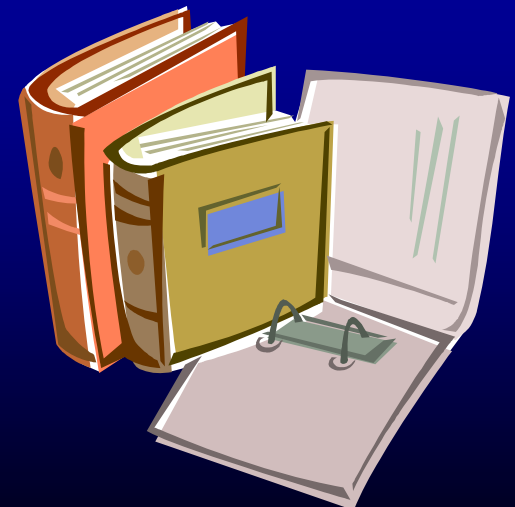
Counselors

MOH TT QC Sample Log

QC SAMPLE LOG

| Date and Time | Tester | QC samples Lot # | Determine® | | | Uni-Gold™ | | | Stat-Pak | | |
|---------------|--------|------------------|------------|---------|--------|-----------|---------|--------|----------|---------|--------|
| | | | Lot # | Ex Date | Result | Lot # | Ex Date | Result | Lot # | Ex Date | Result |
| | | Pos | | | | | | | | | |
| | | Neg | | | | | | | | | |
| | | Pos | | | | | | | | | |
| | | Neg | | | | | | | | | |
| | | Pos | | | | | | | | | |
| | | Neg | | | | | | | | | |
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| | | Neg | | | | | | | | | |

- Fill accurately
- Write legibly
- Date
- Sign



Lab workers



Health workers

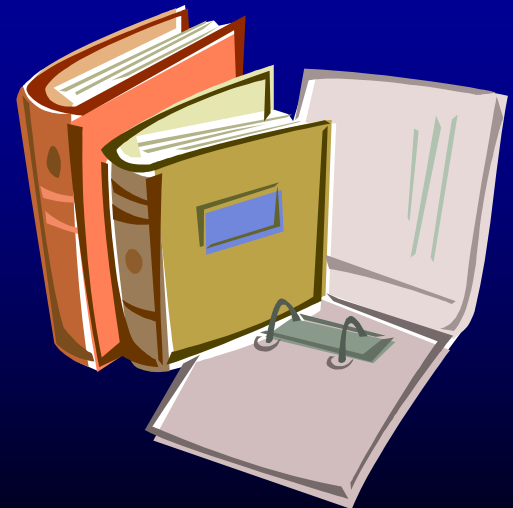


Counselors

MOH TT Rapid Test SOPs

Three HIV Rapid Test SOPs are needed at each MOH TT testing site:

- Determine
- Uni-Gold
- Stat-Pak



Lab workers



Health workers



Counselors

MOH TT SOP: Determine Test

Determine® HIV-1/2 SOP

Summary of the manufacturer's working protocol for Determine® Rapid Tests.

Procedure

1. Check the expiration date. Do not use expired kits.
2. Remove the protective kit cover from the test device.
3. Label test device with the appropriate patient/client identification.
4. Apply two drops of whole blood to the sample pad marked by an arrow symbol.
5. Wait one minute until blood is absorbed into the sample pad.
6. Apply 1 drop of Chase Buffer to the sample pad.
7. Wait at least 15 minutes (up to 60 minutes) and read the result.
8. Record results on the worksheet

Interpretation of Test Results (Only three results are possible with this test):

Positive (Two bands)

Red bands appear in both the control window (labeled 'C') and the patient window (labeled 'P') of the strip. Any visible red color in the patient window should be interpreted as positive.

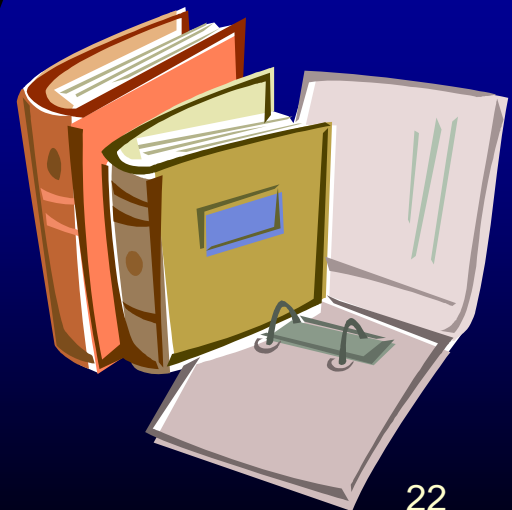
Negative (One Band)

One red band appears in the control window of the strip (labeled 'C') and no red band appears in the patient window of the strip (labeled 'P').

Invalid (No Band)

If there is no band in the control window of the strip the test is invalid. Even if a red band is present in the patient window of the strip, the result is invalid and should be repeated.

- Approved for use in-country
- Must be kept up-to-date
- Must be followed precisely



MOH TT SOP: Uni-Gold Test

Uni-Gold™ HIV SOP

Summary of the manufacturer's working protocol for Uni-Gold™ HIV Rapid Tests.

Procedure

1. Check the expiration date. Do not use expired kits.
2. Remove the protective kit cover from test device.
3. Label test device with the appropriate patient/client identification.
4. Apply two drops of whole blood to the sample well.
5. Apply 2 drops of Wash Reagent to the sample well.
6. Read results after 10 minutes (up to 20 minutes).
7. Record results on the worksheet.

Interpretation of Test Results (Only three results are possible with this test):

Positive (Two bands)

Red bands appear in both the control area (labeled 'C') and the test area (labeled 'T') of the device. Any visible red color in the test area should be interpreted as positive.

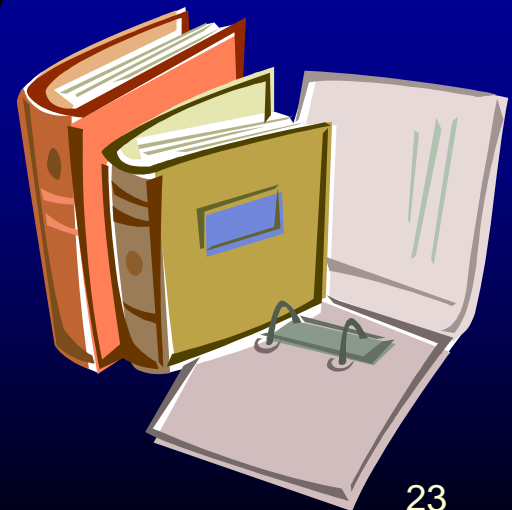
Negative (One Band)

One red band appears in the control area of the device (labeled 'C') and no red band appears in the test area of the device (labeled 'T').

Invalid (No Band)

If there is no band in the control area of the device, the test is invalid. Even if a red band is present in the test area of the device, the result is invalid and should be repeated.

- Approved for use in-country
- Must be kept up-to-date
- Must be followed precisely



Lab workers



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MOH TT SOP: Stat-Pak Test

HIV1/2 Stat Pak SOP

Summary of the manufacturer's working protocol for HIV1/2 Stat-Pak Rapid Tests.

Procedure

1. Check the expiration date. Do not use expired kits.
2. Remove the protective kit cover from the device.
3. Label the device with the appropriate patient/client identification.
4. Collect blood sample with the 5 µl loop provided.
5. Touch the loop to the center of the sample well and wait 3 seconds.
6. Slowly add three drops of buffer to the sample well.
7. Read results after 10 minutes (up to 20 minutes).
8. Record results on the worksheet.

Interpretation of Test Results (Only three results are possible with this test) :

Positive (Two bands)

Red bands appear in both the control area (labeled 'C') and the test area (labeled 'T') of the device. Any visible red color in the test area should be interpreted as positive.

Negative (One Band)

One red band appears in the control area of the device (labeled 'C') and no red band appears in the test area of the device (labeled 'T').

Invalid (No Band)

If there is no band in the control area of the device, the test is invalid. Even if a red band is present in the test area of the device, the result is invalid and should be repeated.

- Approved for use in-country
- Must be kept up-to-date
- Must be followed precisely



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MOH TT HIV Rapid Test Report

HIV RAPID TEST REPORT

Client Name: _____

Client ID: _____

Client DOB: _____

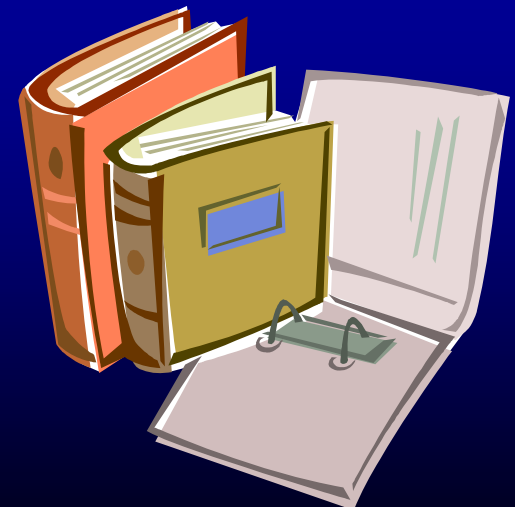
Client Gender: M () F ()

Tester Name: _____

Testing Location: _____

| Rapid test | Determine® | Uni-Gold™ | Stat-Pak |
|------------|------------|-----------|----------|
| Lot # | | | |
| Exp date | | | |
| Result | | | |
| | | | |
| HIV Status | | | |

- Fill accurately
- Write legibly
- Date
- Sign



Lab workers

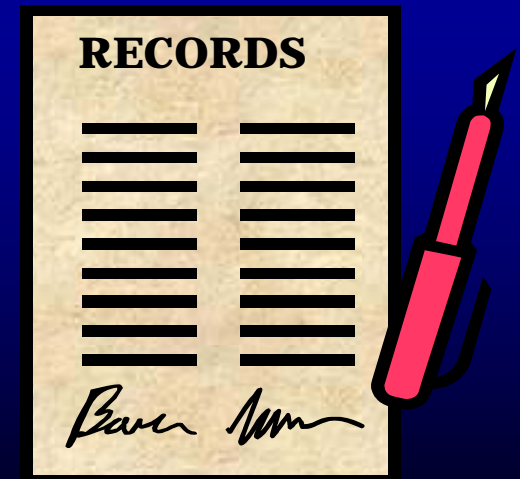


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MOH TT Records



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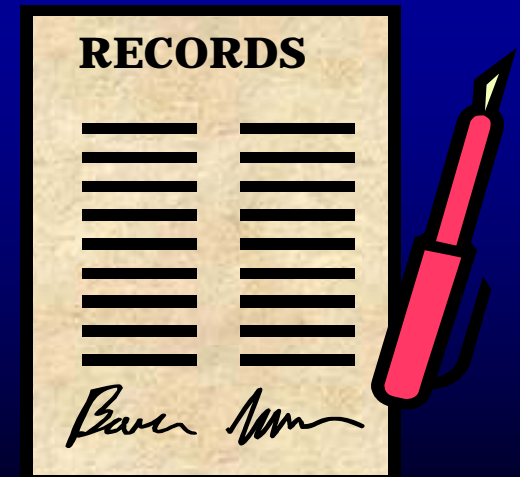
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What Records Are Essential at MOH TT Test Sites?

- Temperature Logs
- QC Sample Logs
- Client test results
- Inventory records



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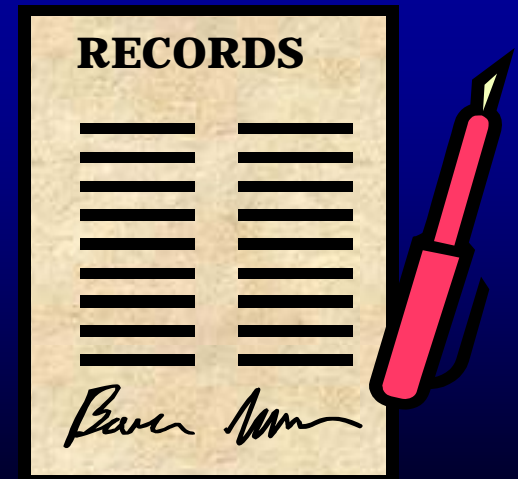


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Proper Record-Keeping Results in Quality Testing

Record-keeping allows a test site to:

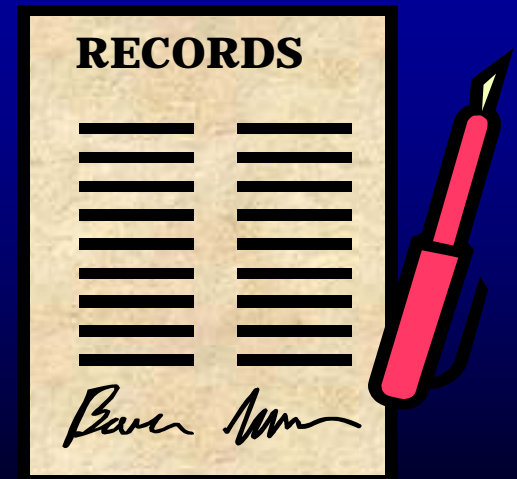
- Communicate accurately and effectively
- Quickly identify problems
- Minimize error
- Monitor quality system
- Assist management in:
 - Developing policy & plans
 - Monitoring and evaluating programs



Tips for Good Record Keeping

- Understand the information to be collected
- Record the information every time
- Record all the information
- Record the information in the same way every time

* PMTCT Generic Curriculum



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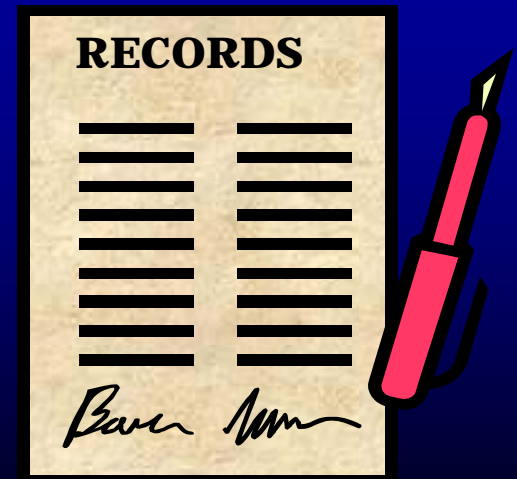


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How Long Should You Retain Client Test Records?

It depends on several factors:

- National policies
- Secure storage space at test site



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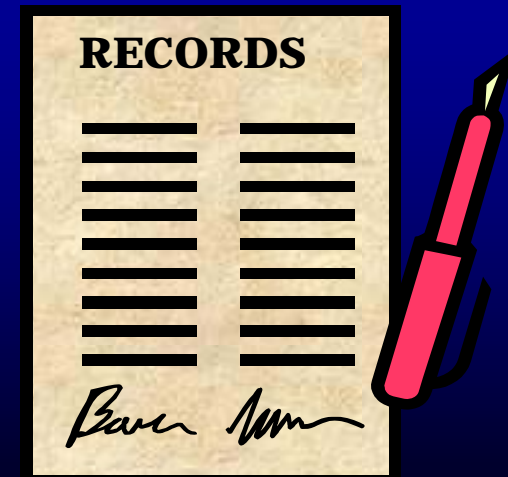
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Records Should be Permanent, Secure, Traceable

- **Permanent:**
 - Keep books bound
 - Number pages
 - Use permanent ink
 - Control storage
- **Traceable:**
 - Sign and date every record
- **Secure:**
 - Maintain confidentiality
 - Limit access
 - Protect from environmental hazards



Information Recorded will Feed Into Monitoring and Evaluation Systems

- Provide in-country information:
 - When will what be reported?
 - How will it be reported?
 - Whom will it be reported to?
 - How will the data be used?



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Summary

- What is a document?
- What is a record?
- List records used at MOH TT testing sites.
- What are SOPs?
- Why are SOPs important?
- What are some tips for good record-keeping?
- How should records be maintained?



Key Messages

- Written policies and procedures are the backbone of the quality system
- Complete quality assurance records make quality management possible
- Keeping records facilitates meeting program reporting requirements



Module 16:

Professional Ethics



Learning Objectives

By the end of the module, you will be able to:

- Describe ethical issues related to HIV rapid testing
- Explain the importance of professional ethics
- Apply ethical conduct to HIV rapid testing
- Take appropriate actions to maintain client confidentiality



Content Outline

- What is ethics?
- Why is ethics important?
- Who is responsible for ethics?
- How is ethics applied to HIV rapid testing?
- Maintaining confidentiality
- Code of conduct



Scenario I

A pregnant woman comes for HIV testing. Your test site has just run out of the 2nd test in the algorithm. You tell her that she will have to come back in 2 days. She becomes very emotional and explains that she has traveled a long distance after finally deciding to get tested and won't be back in the area for a long time.

Feeling sorry for her, you proceed to perform test one, and report a resulting positive test to the client.



Scenario II

At the HIV rapid testing site, you discover that you just run out of the buffer for Test 1 of the algorithm. Rather than denying testing to clients, you decide to go ahead and perform Test 1 using the buffer from kits of Test 2.



Scenario III

Today is Monday. You discover that there are enough test devices to last through the entire week, but they will expire on Wednesday.

Since resources are tight and you don't want to waste any test kits (it is only a couple of days past expiration anyway), you decide to use the test devices until the end of the week.



What Could Be the Consequences of...

- A false positive HIV result?
- A false negative result?



What Is Ethics?

“A set of principles of right conduct”



Why is Ethics Important?

“Decisions about diagnosis, prognosis and treatment are frequently based on results and interpretations of laboratory tests. Irreversible harm may be caused by erroneous tests.”

International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)



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Scenario IV

Rick, the tester, is excited about getting home at the end of his work day, because a relative he hasn't seen in quite some time is scheduled to arrive. Right before he is ready to leave, he gets distracted by a phone call and forgets to lock up the lab register in the cabinet.



Maintaining Confidentiality

It is important to:

- Keep all client/patient information private
- Secure all records / logbooks
- Restrict access to testing areas



Warning

People often violate ethics not because they mean to, but because they are careless. As a matter of fact, they sometimes act with good intentions.



Role-Play

Watch the role-play and discuss:

- What happened?
- What were the ethical issues involved?
- What were the implications?
- What would you do if you were in this situation?



Who is Responsible for Ethics?

- EVERYONE!
 - Medical Laboratory Technician
 - Nurse Counselor
 - Clerk
 - Secretary
 - General Hand
 - Driver



How Do We Apply Ethics To HIV Rapid Testing?

- Work done
- Behavior of the staff
- Behavior of management



Code of Ethics (IFBLS)

Excerpts from International Federation of Biomedical Laboratory Science (IFBLS)

- Maintain strict confidentiality of patient information and test results
- Safeguard the dignity and privacy of patients
- Be accountable for the quality and integrity of clinical laboratory services



Code of Ethics (ASCP)

Excerpts from American Society for Clinical Pathology (ASCP)

- Treat patients and colleagues with respect, care and thoughtfulness
- Perform duties in an accurate, precise, timely and responsible manner
- Safeguard patient information as confidential, within the limits of the law
- Prudently use laboratory resources



Code of Ethics (CASMET)

Caribbean Association of Medical Technologists
(CASMET)

CODE OF ETHICS

On entering at this time into the practice of Medical Technology, I accept with full realization of its implication, the responsibility associated with my duties.

I am aware that since the Physician or Surgeon relies upon my work in the diagnosis and treatment of disease, even an apparent trivial error may affect seriously the health or even the life of a Patient. Every procedure, therefore, must be carried out with thoughtfulness and accuracy.

Knowing these things I recognize that my integrity and that of my profession must be pledged to the absolute reliability of my work.

I am aware of the need for co-operation and friendly understanding between my fellow workers and myself and for the patience, humanity and tact which must be exercised toward the patient who by reason of his illness is particularly needful of my skill and kindness.

I realize that the knowledge obtained concerning persons in the course of my work is privileged and confidential and that since the Physician or Surgeon has the ultimate responsibility in diagnosis and treatment, my results may be made known only to him or another having duly constituted authority.

To these principles I hereby subscribe, promising to conduct myself at all times in a manner appropriate to the dignity of my profession.



Features of CASMET Code of Ethics

Testing is

- Thoughtful and accurate
- Reliable
- Confidential



Summary

- In your own words, what is ethics?
- Why is it important?
- Give examples of actions you can take to maintain client confidentiality.
- Give an example of a code of ethics to which you are willing to personally commit.



Key Messages

- Ethical issues are important. We must constantly remind ourselves of the code of conducts and ensure we do the right thing.
- Ethical issues are often hard to deal with because they create dilemmas.
- People often violate ethics not because they mean to, but because they are careless. As a matter of fact, they sometimes act with good intentions.

